SUPREME COURT OF THE STATE OF NEW YORK

COUNTY OF SUFFOLK

IN RE OPIOID LITIGATION

_____/ No. 400000/2017

-- HIGHLY CONFIDENTIAL --

VIDEOTAPED DEPOSITION OF ANNA LEMBKE, M.D.

San Francisco, California

Thursday, January 16, 2020

REPORTED BY:

LESLIE ROCKWOOD ROSAS, RPR, CSR 3462

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK

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Videotaped deposition of ANNA LEMBKE, M.D., taken on behalf of Defendants, at the law offices of Lieff Cabraser Heimann & Bernstein, LLP, 275 Battery Street, Suite 2900, San Francisco, California, beginning at 8:06 A.M. and ending at 5:27 P.M., on Thursday, January 16, 2020, before Leslie Rockwood Rosas, RPR, Certified Shorthand Reporter No. 3462.

APPEARANCES:

FOR THE PLAINTIFF:
LIEFF CABRASER HIEMANN & BERNSTEIN, LLP
BY: DONALD C. ARBITBLIT, ESQ.
ABBY WOLF, ESQ.
BRITT CIBULKA, ESQ. (via speakerphone)
275 Battery Street, Suite 2900
San Francisco, California 94111-3339
415.956.1000
darbitblit@lchb.com
awolf@lchb.com
bcibulka@lchb.com

STATE OF NEW YORK, OFFICE OF THE ATTORNEY GENERAL
BY: LEO O'TOOLE, ESQ. (via speakerphone)
200 Old Country Road, Suite 240
Mineola, New York 11501
516.248.3302

APPEARANCES (Continued):

FOR THE PLAINTIFF COUNTY OF NASSAU:
NAPOLI SHKOLNIK PLLC
BY: SALVATORE C. BADALA, ESQ. (via speakerphone)
400 Broadhollow Road, Suite 305
Melville, New York 11747
212.397.1000
sbadala@napolilaw.com

FOR THE DEFENDANT JOHNSON & JOHNSON AND JANSSEN:
O'MELVENY & MYERS LLP
BY: HOUMAN EHSAN, M.D.
400 South Hope Street, 18th Floor
Los Angeles, California 90071-2899
213.430.6326
hehsan@omm.com

APPEARANCES (Continued):

FOR THE DEFENDANT CARDINALHEALTH:
WILLIAMS & CONNOLLY LLP
BY: MATTHEW P. MOONEY, ESQ.
STEVEN M. PYSER, ESQ.
725 Twelfth Street NW
Washington, DC 20005
202.434.5421
mmooney@wc.com
spyser@wc.com

FOR THE DEFENDANT WALMART:
JONES DAY
BY: EDWARD M. CARTER, ESQ.
325 John H. McConnell Boulevard, Suite 600
Columbus, Ohio 43215-2673
614.281.3906
emcarter@jonesday.com

APPEARANCES (Continued):

FOR THE DEFENDANT WALGREENS:
BARTLIT BECK LLP
BY: KATHERINE M. SWIFT, ESQ.
54 West Hubbard Street
Chicago, Illinois 60654
312.494.4405
Katherine.Swift@BartlitBeck.com

FOR THE DEFENDANT AMERISOURCEBERGEN:
REED SMITH
BY: LUKE PORTER, ESQ.
101 Second Street, Suite 1800
San Francisco, California 94105
415.659.5987
lporter@reedsmith.com

APPEARANCES (Continued):

FOR THE DEFENDANT ENDO PHARMACEUTICALS, INC., ENDO HEALTH SOLUTIONS, INC., PAR PHARMACEUTICAL, INC., AND PAR PHARMACEUTICAL COMPANIES:
ARNOLD & PORTER KAY SCHOLER LLP
BY: ANGELA R. VICARI, ESQ.
250 West 55th Street
New York, New York 10019-9710
212.836.7408
angela.vicari@arnoldporter.com

FOR THE DEFENDANT MALLINCKRODT:
ROPES & GRAY LLP
BY: ROCKY C. TSAI, ESQ.
Three Embarcadero Center
San Francisco, California 94111-4006
415.315.6358
Rocky.Tsai@ropesgray.com

APPEARANCES (Continued):

FOR THE DEFENDANT ALLERGAN FINANCE:
KIRKLAND & ELLIS LLP
BY: MARIA PELLEGRINO RIVERA, ESQ.
300 North LaSalle
Chicago, Illinois 60654
312.8622740
mrivera@kirkland.com

FOR THE DEFENDANT MCKESSON:
COVINGTON & BURLING LLP
BY: MEGAN L. RODGERS, ESQ.
3000 El Camino Real
5 Palo Alto Square
Palo Alto, California 94306-2112
650.632.4734
mrodgers@cov.com

APPEARANCES (Continued):

FOR THE DEFENDANT TEVA AND ACTAVIS AND GENERIC ENTITIES:
MORGAN & LEWIS
BY: MARTHA A. LEIBELL, ESQ.
200 South Biscayne Boulevard, Suite 5300
Miami, Florida 33131-2339
305.415.3387
martha.leibell@morganlewis.com

FOR THE DEFENDANT ROCHESTER DRUG COOPERATIVE, INC.:
ALLEGAERT BERGER & VOGEL
BY: LAUREN J. PINCUS, ESQ. (via speakerphone)
111 Broadway, 20th Floor
New York, New York 10006
212.616.7057
lpincus@abv.com

Also Present: Sean Grant, Videographer

I N D E X

THURSDAY, JANUARY 16, 2020

QUESTIONS WITNESS INSTRUCTED NOT TO ANSWER:

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DEPOSITION EXHIBITS
ANNA LEMBKE, M.D.

San Francisco, California; Thursday, January 16, 2020
8:06 A.M.
PROCEEDINGS
--oOo--

(Exhibit 1, Court Order, Hon. Jerry Garguilo, 1/14/20, marked for identification.)

(Exhibit 2, Expert Report, Anna Lembke, M.D., 12/19/19, marked for identification.)

THE VIDEOGRAPHER: Good morning. We're on the record. The time is 8:06 a.m. The date is January 16, 2020.

This begins the videotaped deposition of Dr. Anna Lembke, M.D. This deposition is being taken on behalf of counsel for defendants, In Re Opioid Litigation.

This case is filed in the Superior Court of the State of New York, County of Suffolk, Index Number 400000/2017.

This deposition is being held at Lieff Cabraser Hiemann & Bernstein in San Francisco, California.

My name is Sean Grant from the firm Veritext. I'm the videographer, and the court reporter is Leslie Rockwood, also from Veritext.

Please note that audio and video recording will take place unless all parties have agreed to go off the

record. Microphones are sensitive and may pick up whispers, private conversations or cell interference.

(Telephonic interruption.)

THE VIDEOGRAPHER: Would all present in the room please identify themselves and state whom they represent.

Counsel.

MR. MOONEY: Matthew Mooney, Williams & Connolly, for CardinalHealth. And next to me is Steve Pyser, also of Williams & Connolly.

MR. EHSAN: Houman Ehsan, O'Melveny & Myers, on behalf of Johnson & Johnson and Janssen.

MR. CARTER: Ed Carter for Walmart.

MS. SMITH: Kate Swift for Walgreens.

MR. PORTER: Luke Porter, Reed Smith, on behalf of AmerisourceBergen.

MS. VICARI: Angela Vicari from Arnold & Porter for ENDO Pharmaceuticals, Inc., ENDO Health Solutions, Inc., Par Pharmaceutical, Inc., and Par Pharmaceutical Companies.

MR. TSAI: Rocky Tsai, Ropes & Gray, for Mallinckrodt.

MS. RIVERA: Maria Rivera from Kirkland & Ellis on behalf of Allergan Finance.

MS. RODGERS: Megan Rodgers, with Covington & Burling, on behalf of McKesson.

MS. LEIBELL: Martha Leibell of Morgan & Lewis for the Teva and Actavis generic entities.

MS. WOLF: Abby Wolf on behalf of plaintiffs.

MR. ARBITBLIT: Don Arbitblit, Lieff Cabraser Hiemann & Bernstein, for plaintiffs.

THE VIDEOGRAPHER: Is there anybody appearing telephonically?

MR. O'TOOLE: Yes. Leo O'Toole, from the Office of the New York State Attorney General on behalf of plaintiff.

THE VIDEOGRAPHER: Okay, Leo O'Toole? One more time, Leo.

MR. O'TOOLE: Leo O'Toole, from the Office of the New York State Attorney General, on behalf of plaintiff.

THE VIDEOGRAPHER: Thank you.

Next? Anyone else?

MR. BADALA: Sal Badala -- Sal Badala from Napoli Shkolnik on behalf of Nassau County.

THE VIDEOGRAPHER: Is that it? Thank you.

MS. PINCUS: Lauren Pincus -- oh -- Lauren Pincus, from Allegaert Berger & Vogel, on behalf of defendant Rochester Drug Cooperative, Inc.

THE VIDEOGRAPHER: Anyone else?

MS. CIBULKA: Britt Cibulka, from Lieff Cabraser Hiemann & Bernstein, on behalf of plaintiffs.

THE VIDEOGRAPHER: Anyone else? Thank you.

Would the Certified Court Reporter please swear in the witness.

THE REPORTER: Would you raise your right hand, please.

You do solemnly state that the evidence you shall give in this matter shall be the truth, the whole truth and nothing but the truth, so help you God?

THE WITNESS: Yes, I do.

THE REPORTER: Thank you.

THE VIDEOGRAPHER: Counsel.

EXAMINATION

Q. BY MR. MOONEY: Good morning, Dr. Lembke.

A. Good morning.

Q. Before we get started, I just want to put on the record that on January 14th of this month, the Court entered a short form order that concerns the conduct of expert depositions, and I've spoken to your counsel here and he assured me that he's aware of the order.

And so we've been instructed to place the order from Justice Garguilo on the record, and so I'm going to offer that as Exhibit 1 to your deposition.

Would you please state your name for the record.

A. Anna Lembke.

Q. And you are a professor at Stanford University School of Medicine; is that right?

A. Yes.

Q. What is your current title at Stanford?

A. I'm an associate professor. I'm medical director of addiction medicine. I'm program director of our addiction medicine fellowship, and I'm chief of our addiction medicine dual diagnosis clinic. I also have a courtesy appointment in the Department of Anesthesia Pain.

Q. And how long have you taught at Stanford?

A. I've been teaching at Stanford for over 20 years.

Q. And would you please briefly walk through your educational background.

A. I did my undergraduate at Yale University, graduating summa cum laude, Bachelor's in humanities. I then attended Stanford Medical School, where I graduated with an M.D. in 1995.

I then completed a residency in psychiatry in 2000 and did a fellowship in mood disorders in the early aughts at the same time that I joined as junior faculty at Stanford, and I've been there on faculty at the university and the School of Medicine since that time.

Q. And you were retained by the plaintiffs to

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provide an expert report in this litigation; is that correct?
A. That is correct.
Q. And did you create such a report?
A. Yes, I did.
Q. I'm going to show you what's been marked as Exhibit 2 to your deposition. Would you please take a moment to look at it.
A. (Witness complies.)
Q. Would you please identify what's been handed to you as Exhibit 2?
A. This is my expert report, which I submitted on December 19, 2019, in this litigation.
Q. And does the report that's been identified as Exhibit 2 contain the opinions you intend to offer in this litigation?
A. It's a long report so it's hard for me to assess whether it's exactly what I submitted, but I assume that it is, and yes, it appears to contain my opinions.
Q. I will represent to you that this is -- I printed the PDF that we received from plaintiffs. So assuming that's true, does it contain the opinions you intend to offer in this litigation?
A. Yes.
Q. And does this report contain a comprehensive

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explanation of the opinions you intend to offer in this litigation?
A. It does contain my opinions, yes.
Q. And is it a comprehensive set of your opinions?
A. What do you mean by "comprehensive"?
Q. Well, are there other opinions that you didn't offer in your report that you intend to offer in this litigation?
A. No.
Q. When did the plaintiffs in this case retain you as an expert?
MR. ARBITBLIT: Objection. Just to clarify -- and I won't do speaking objections, but we're going back to the MDL or do you mean New York?
MR. MOONEY: In New York. I'll clarify. Just for everyone, I'll clarify when I'm talking about the Federal litigation.
THE WITNESS: I was first approached in November of 2019 to be an expert witness in this litigation.
Q. BY MR. MOONEY: Are you paid by the hour?
A. Yes, I am.
Q. What is your hourly rate?
A. $500 per hour.
Q. And how about for your time testifying?
A. $800 per hour.

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Q. You've been paid more than $20,000 by the plaintiffs in the New York litigation so far; is that correct?
A. I'm not sure.
Q. How much do you think you have been paid by the plaintiffs in the New York litigation so far?
A. I think it is more than $20,000 so far.
Q. Now, you also submitted a report in the Federal multi-district litigation; is that correct?
A. Yes, I did.
Q. Did the plaintiffs in the Federal opioid litigation also pay you for your time?
A. Yes, they did.
Q. The plaintiffs in the Federal opioid litigation paid you more than $200,000 for your opinions; is that correct?
MR. ARBITBLIT: Objection to form.
And just to clarify, is this a reciprocal -- have there been any agreements you're aware of as far as providing evidence on both sides as to what experts have been paid? Because if not, I'll object and instruct not to answer until there's -- there is an agreement.
MR. MOONEY: We received the expert -- or the invoices from Dr. Lembke's Federal District case -- or Federal litigation. I'm just confirming that the numbers

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that are on that invoice are what she was paid.
MR. ARBITBLIT: I'll still object to the form of the question, but you can answer.
THE WITNESS: I must admit I have not added it up so I don't know the exact amount.
Q. BY MR. MOONEY: Can you provide an estimate of how much the plaintiffs paid you in the Federal litigation for your opinion?
MR. ARBITBLIT: Object to form.
THE WITNESS: I really don't know.
Q. BY MR. MOONEY: Have you received any other payments from plaintiffs in other opioid-related litigation?
A. Yes, I have.
Q. Who -- who has paid you in other opioid litigation?
A. The State of Washington.
Q. And how much has the State of Washington paid you?
MR. ARBITBLIT: Object to form.
And again, if there's reciprocal agreement that all payments to defense experts are fair game and will be answered, then I'll allow the witness to answer. If not, I'll instruct her not to.
And that goes for everyone around the table. If

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there's an agreement, she can answer; if there isn't, she won't.
MR. PYSER: I'll jump in. This is Steven Pyser.
The question pending, we can talk off-line -- there's a lot of defendants -- about whether there's agreements across all of the cases. To my knowledge, there's not. But there is no sound basis for an objection here.
The question's pending. It's a simple question. There's no basis not to -- to instruct not to answer.
MR. ARBITBLIT: I disagree. We don't -- we don't agree with that.
Don't answer.
Q. BY MR. MOONEY: Turn to page 5 and 6 of your report.
Dr. Lembke, are you going to follow your counsel's advice not to answer the question?
A. Yes, I am.
Q. On pages 5 and 6, you'll see a series of nine opinions.
Do you see that?
A. Yes, I do.
Q. On page 6, paragraph 9: "Today's opioid crisis would not have occurred without the paradigm shift that contributed in overprescribing an excessive supply of

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opioids, which together contributed to the scourge of addiction and death."
Did I read that correctly?
A. No.
Q. Would you read paragraph 9.
A. "Today's opioid crisis would not have occurred without the paradigm shift that resulted in overprescribing an excessive supply of opioids, which together contributed to the scourge of addiction and death."
Q. And is it your opinion that today's opioid crisis would not have occurred without a paradigm shift that resulted in overprescribing an excessive supply of opioids?
A. Yes, that is my opinion.
Q. When you say "the paradigm shift" in paragraph 9, what are you referring to?
A. I'm referring to a change in our society leading to massive oversupply of opioids, putting the population at risk.
Q. And is that paradigm shift a paradigm shift in the treatment of pain?
A. That paradigm shift included both a shift in the treatment of pain as well as an efficient distributor supply chain that enabled those pills to be distributed

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to every region in the country and readily dispensed.
Q. What is the paradigm shift in the distributor supply chain?
A. The paradigm shift in the distributor supply chain is the collaboration between distributors and pharmacies and opioid manufacturers that led to a massive increase in the number of pills, putting the population at risk.
Q. Do you have any expertise in supply chain management?
MR. ARBITBLIT: Object to form.
THE WITNESS: I am familiar with the path of opioid pills from manufacturers to distributors to pharmacies to patients. I've spent the last 20 years as a practicing physician. I've also researched the opioid epidemic.
And so based on that, I do have expertise in understanding how that supply chain has contributed to the oversupply of opioids.
Q. BY MR. MOONEY: Have you ever worked in a pharmaceutical wholesale distributor?
A. No I have not.
Q. Have you ever worked in a pharmacy?
A. No, I have not.
Q. Have you ever worked for a pharmaceutical

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manufacturer?
A. No, I have not.
Q. Have you ever taken coursework in supply chain management?
A. No.
Q. Have you taken -- are you -- have you taken any coursework relating to pharmaceutical distributors' regulatory responsibilities?
A. No, I have not.
Q. Do you have any -- have you taken any coursework regarding the wholesale distribution of controlled substances?
A. No.
Q. Do you have any expertise concerning the regulatory responsibilities rela- -- excuse me. Strike that.
Do you have any expertise concerning the monitoring of suspicious orders by pharmacies?
A. I do have expertise in the sense that I am aware that the failure to scrutinize the distribution of opioid pills in large volumes has contributed to the current opioid epidemic.
Q. And what is that awareness based on?
A. That's based on reports of billions of pills being disseminated across this country, including to

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small towns consisting of no more than 10,000 citizens, amounts of pills that could never possibly be justified by the need for analgesia in that community.
Q. Anything else?
A. It's also based on my clinical experience over 20 years observing the increased supply leading to ready access, an endangerment of individuals due to that increased supply, increasing their vulnerability to addiction and accidental overdose death.
Q. Anything else?
A. Could you repeat the question?
Q. Anything else?
A. Could you repeat the root question?
Q. What is the -- what is your awareness of the failure to scrutinize the distribution of opioid pills in large volumes that has contributed to the opioid epidemic?
A. My awareness also comes from reports that have been issued on ARCOS data and DEA supply-chain data.
Q. Anything else?
A. My awareness is also based on knowledge of pill mills.
Q. Can you identify any pill mills in the state of New York?
A. I'm not aware of any pill mills in the state of

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New York.
Q. Have you conducted any independent analysis relating to the failure to scrutinize the distribution of opioid pills in large volumes?
MR. ARBITBLIT: Object to form.
THE WITNESS: What do you mean by "independent analysis"?
Q. BY MR. MOONEY: Well, you said that you're aware of reports from ARCOS data or reports on the number of pills that have been shipped.
My question is: Have you done any of your own analysis to reach a conclusion about the distribution of opioids?
A. I have not done my own numeric analysis of those data.
Q. You were relying on what you have read in newspaper reports?
A. Newspaper reports and other reports as well.
Q. Okay. What other reports?
A. I'd like to refer to my report.
Q. Are you not familiar, sitting here today, with the contents of your report?
A. I'm very familiar, but this is a very serious proceeding and I want to be as accurate as I possibly can.

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So the NASEM report, which I refer to on page 12 of my report, found that diversion is a key contributor to increased exposure to prescription opioids, and I'm quoting here from the NASEM report, quote: "DEA reports that in recent years distributors in the United States dispersed 12 to 15 billion dosage units of opioid narcotics to retail-level purchasers, suggesting that total diversion is on the order of 2.5 to 4 billion dosage units," unquote.
Also a Washington Post analysis of Federal ARCOS data shows that from 2006 to 2012, approximately 76 billion oxycodone and hydrocodone pills were delivered in the United States.
And if we were to assume the same rate of diversion as from the NASEM report, that would represent diversion on the order of 12 to 19 billion pills during the six-year period from 2006 to 2012.
There was also a more recent Washington Post report adding the years 2013 and 2014, bringing that total number of disbursed pills up to 100 billion pills. And that's based on ARCOS data.
Q. How many --
A. Oh, sorry. I was just going to say, I also base my opinion on the impact of distribution on the opioid epidemic on studies showing that in regions in the

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United States where more pills were disbursed were also regions that saw increased rates of harm due to opioid, including opioid addiction overdose deaths.
And I do refer to that in my report, and I'd like to find that reference and also include it in my response.
So on page 85 of my report, I talk about how based on an article by Ghertner, et al., that: "ARCOS data on opioid prescribing shows a 9-percent increase in opioid hospitalizations for each 1 morphine kilogram equivalent increase in opioid sales at the county level. These data demonstrate a clear and convincing geographic specific link between opioid dispensing and opioid-related harm."
Q. Opioid prescribed -- this paragraph E references opioid prescribing; is that right?
MR. ARBITBLIT: Object to form.
THE WITNESS: It references opioid sales at the county level.
Q. BY MR. MOONEY: In paragraph E of page 85: "ARCOS data on opioid prescribing showing 9-percent increase in opioid-related hospitalizations for each 1 morphine kilogram equivalent increase in opioid sales at the county level."
Is that right?

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A. Yes, that's right.
Q. And do you agree that opioid sales from a pharmacy would not -- do not happen without a prescription?
A. Pharmacies also have a responsibility in the opioid supply chain to make sure that patient consumers are not being harmed by the opioids that are dispensed. So although I would agree that pharmacies cannot dispense opioids without a prescription, I would qualify that to say that they also have a responsibility to patient consumers to ensure that it's an appropriate prescription and that it's a true prescription, it's not a prescription that will harm the patient.
Pharmacists do have a responsibility, for example, to check drug interactions to check relative contraindications.
Pharmacists play an important role in educating their patients about the risks and benefits of the medications they're dispensing. So pharmacists are not merely in a passive role of turning over opioids or other medications when they get a prescription. They have also a health-safety relationship to their patients.
MR. CARTER: This is Ed Carter.
I move to strike everything in that response other than "I would agree pharmacies cannot dispense

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opioids without a prescription."
MR. MOONEY: And I will just repeat the question, understanding you have a caveat.
Q. My question was -- was simpler: Do you agree that opioid sales from a pharmacy do not happen without a prescription?
MR. ARBITBLIT: Object to form.
THE WITNESS: I agree, with the caveat stated previously.
Q. BY MR. MOONEY: If you could turn to page 13 of your report. Paragraph 2: "Opioid prescribing began -- began to increase in the 1980s, became prolific in the 1990s and the early part of the 21st century, representing a radical paradigm shift in the treatment of pain and creating more access to opioids across the United States."
Did I read that correctly?
A. Yes, you did.
Q. Is that the opinion that you have in this case?
A. That is one of nine opinions that I have in this case.
Q. And so prior to 1980, doctors used opioid pain relievers sparingly; is that right?
A. Yes.
Q. And then there was a change in how doctors

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prescribed opioids?
A. Yes.
Q. And you say that that change was radical?
A. Yes.
Q. What do you mean by there was a radical change in the way that doctors treated pain?
A. Prior to 1980, doctors used opioids sparingly for acute pain for people in extreme agony and at the end of life. Starting in the 1980s, particularly in the 1990s, that paradigm changed such that opioids became first-line treatment for even minor and chronic pain conditions.
Q. Does that mean that a responsible physician trying to act in good faith in treating his or her patients would have prescribed opioids more often than in the past?
MR. ARBITBLIT: Object to form.
THE WITNESS: What it means is that several generations of physicians were misled in terms of what the science showed regarding safety and efficacy of opioids, and in believing that they were prescribing according to good science, they began to prescribe opioids for minor and chronic pain conditions in a departure from past practice.
Q. BY MR. MOONEY: And that departure was that

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opioids would be prescribed more frequently than in the past; is that correct?
A. That's correct.
Q. Is it your opinion that the change in medical practice toward liberal opioid prescribing has been a major factor contributing to the increased supply which has fueled the opioid epidemic?
A. It's my opinion that the change in opioid prescribing has been a major factor, but not the only factor. Another major factor has been an efficient distributor supply chain as well as the problem of diversion of opioids through various means.
Q. Is it your understanding that pharmaceutical distributors ship prescription drugs to pharmacies when a pharmacy places an order for those drugs?
A. Yes, that is my understanding.
Q. Is it your understanding that pharmacies order prescription drugs from distributors based on the pharmacy's expected demand?
A. Yes, that's my understanding.
Q. And in the case of prescription drugs, a pharmacy's expected demand will depend on how many customers come to the pharmacy with a doctor's prescription for those drugs, doesn't it?
MR. ARBITBLIT: Object to form.

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THE WITNESS: I'm actually not that familiar with what the pharmacies base their orders on.
Q. BY MR. MOONEY: Do you have any understanding of pharmacy inventory management practices?
A. That's not my area, no.
Q. You keep referencing an efficient supply chain, but no matter how efficient the supply chain is, without a prescription, those pills are just going to sit on the shelf, aren't they?
MR. ARBITBLIT: Object to form.
THE WITNESS: The efficient distributor supply chain has played a major role in this epidemic. Without the massive distribution of opioid pain pills to every geographic region in the United States, this epidemic would have been much less likely to occur and perhaps may not have occurred at all.
So what your question assumes is that the distributors are just innocently fulfilling orders, that they're just the trucks, and that's not really an accurate representation. Because they, too, have a responsibility in scrutinizing suspicious orders and being vigilant stewards of highly lethal drugs that they're distributing and dispensing across the country.
Q. BY MR. MOONEY: These highly lethal drugs, these are the opioids you're talking about?

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A. That's right.
Q. And those are FDA-approved drugs?
A. Yes, they are.
Q. And the FDA, even today in 2020, allows opioids to be prescribed to patients; is that right?
A. Yes, it does.
Q. And is there anything about the efficient supply chain that is unique to opioids as opposed to any of the other numerous drugs that distributors distribute to pharmacies?
MR. ARBITBLIT: Object to form.
THE WITNESS: Yes, I think so.
Q. BY MR. MOONEY: What is unique about the opioid supply chain that makes it efficient?
A. One thing that is unique to the opioid supply chain is the way that all of the actors from manufacturers to distributors to pharmacies, benefitted from the actions of the others in terms of increasing demand and increasing supply.
Q. How is that unique to opioids as opposed to any other pharmaceutical product?
A. Because in the case of opioids, there was collusion around the fact that people were becoming addicted and dying from these opioids, and yet the opioid pharmaceutical industry turned the other cheek or turned

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a blind eye to that problem and sought to hide behind the other and say it was somebody else's responsibility, when in fact they all had a responsibility. But the money was, you know, so appealing, that these various agencies in the opioid distributor supply chain failed to meet their stewardship responsibility vis-à-vis the American public.
Q. What's the basis for your statement that there was collusion among the members of the supply chain?
A. One small example is I believe that some of the distributors, for example, created coupons for free samples of opioids that patients could get.
Q. Where is that in your report?
A. That is not in my report.
Q. Okay. What documents are you relying on to support the belief that distributors created coupons for free samples of opioids?
A. I've seen documents showing that McKesson created coupons for free samples of Nucynta.
Q. Anything else?
A. No. But the practice of kind of promotional efforts and free coupons and a general collusion between these individuals is something that I feel I have seen in my more than 20 years of medical practice.
I would also add that opioids are unique from

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other medications because of their highly addictive potential and their lethality and the fact that they create a serious dependent syndrome that drives ongoing use, even beyond utility or safety or efficacy.
So I do think that the pharmaceutical industry that is involved in opioids has a responsibility above and beyond what might be there even for other types of medications that are not as addictive and not as lethal.
Q. You say the money was so appealing. What's the profit margin for opioids for a pharmaceutical distributor?
MR. ARBITBLIT: Object to form.
THE WITNESS: I can't give you specific numbers, but my sense is that it's a billion-dollar industry.
Q. BY MR. MOONEY: And what is that based on?
THE WITNESS: That's based on my reading in the public domain.
Q. BY MR. MOONEY: And what are distributors' profits from this so-called billion-dollar industry?
MR. ARBITBLIT: Object to form.
THE WITNESS: I'm not familiar with specific numbers regarding profits.
Q. BY MR. MOONEY: So how do you know that the money was so appealing that it caused the distributors to look the other way?

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A. Because I am aware that this is a billion-dollar -- a multi-billion-dollar industry.
Q. You also say that you said you think the pharmaceutical industry that is involved in opioids has a responsibility above and beyond what there might be even for other types of medications. What do you mean by "a responsibility above and beyond"?
A. Opioids, in a sense, sell themselves because of their addictive potential. So I believe that when it comes to the opioid pharmaceutical industry, they need to be especially vigilant about the problem of opioid addiction overdose death beyond what they would need to be for a non-addictive medication or even an addictive medication that is not an opioid. I think opioids are unique in this way.
Q. And what would that especially vigilant, what would that look like?
A. That would look like being very, very vigilant regarding regions of the country that -- and pharmacies that are ordering especially high volumes of opioids and very closely scrutinizing those pharmacies in those regions to determine whether or not diversion is occurring or whether or not the citizens in that community are being harmed by the opioids that they are ingesting.

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It would involve an additional degree of scrutiny and vigilance and also caution such that if there is a spike or an increase in a specific region in terms of orders for opioid medication, then the opioid pharmaceutical industry has a responsibility to have a very high suspicion for a problem in that community along the lines of addiction, either through a legitimate prescription or addiction through diversion.
Q. How is a distributor supposed to know if a community is experiencing addiction through legitimate prescriptions?
MR. ARBITBLIT: Object to form.
THE WITNESS: The job of a distributor is to assess suspicious orders. Suspicious orders are determined in part by the volume of pills shipped to a given region, a concern for pill mill doctors in that region, a concern for diversion in that region.
So geographic spikes or increases in opioid orders should be a concern for that community being harmed by those opioids.
It's not enough to say that, well, that's what the doctor ordered. That's not sufficient. That reneges on their responsibility.
Sorry, I said "reneges on their responsibility," not "renders."

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Q. When there was a change in the way in which doctors prescribed opioids, was that change limited to a specific type of doctor?
A. No, that was a paradigm shift across all medical specialties.
Q. And by volume, did the family medicine doctors and internal medicine doctors account for most of the opioids that were prescribed?
A. Yes.
Q. And so as you analyzed it in your 2016 article, was the problem of overprescribing the result of a small number of especially big prescribers?
A. The point of that 2016 article was to highlight that the paradigm shift in treatment of pain in medicine over the last three decades has led to all different types of prescribers prescribing more opioids.
Q. And then --
A. None -- nonetheless -- nonetheless, pill mill doctors, or small subsets of prolific prescribers, have also contributed to the problem. They're not the only explanation, but they are a part of the problem.
So it's both pill mill doctors and the broad shift in prescribing that has led to the oversupply of opioids in our communities.
Q. And that shift in prescribing, was that because

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there was a wholesale shift in the generally accepted medical practice as it relates to the treatment of pain?
A. Yes.
Q. You also submitted a report in the Federal multidistrict opioid litigation; is that correct?
A. Yes, that's correct.
Q. Is it fair to say that if you said something in your earlier report but do not include it in your New York report, then you do not intend to offer the earlier opinion in this litigation?
MR. ARBITBLIT: Object to form.
THE WITNESS: Can you rephrase the question?
Q. BY MR. MOONEY: Sure.
So the opinion or the report that you submitted in the New York litigation is not exactly the same as the report that you offered in the Federal litigation; is that right?
A. That's right.
Q. And so my question is: If there are differences, and you said something in the New York report -- or excuse me. Strike that.
If there are differences and you said something in the Federal report and that is not included in your New York report, can we assume that you do not intend to offer the information -- the opinion that was only in the

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Federal litigation report?
A. I would not assume that. I have a very large body of work that predates my involvement in any opioid litigation, and my opinions are based on that body of work, on my clinical experience, as well as my reports. It's -- it's all of a piece.
Q. What opinions in your Federal report that are not in your New York report do you intend to offer in this case?
MR. ARBITBLIT: Object to form.
THE WITNESS: If you could refer to some specific difference between the reports, it would be easier for me to comment.
Q. BY MR. MOONEY: So sitting here today, you can't identify opinions that were in your Federal report that are not in your New York report that you intend to offer in the New York litigation; is that correct?
MR. ARBITBLIT: Object to form.
THE WITNESS: The differences in the two reports are largely structural. The opinions are the same.
Q. BY MR. MOONEY: You also gave a deposition in the Federal litigation?
A. That's right.
Q. And you were under oath?
A. Yes, I was.

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Q. Did you have a chance to review the transcript after the deposition ended?
A. Yes, I did.
Q. Did you have a chance to make changes to your testimony on an errata?
A. Yes, I did.
Q. Is there any statement in the Federal litigation deposition that you now believe to be false?
A. No.
Q. So you stand by what you said in that sworn testimony?
A. Yes.
Q. Do you treat patients with chronic pain?
A. Yes.
Q. Do you prescribe opioids to your patients?
A. Yes.
Q. Have you prescribed opioids to your patients with chronic pain?
A. Yes.
Q. How long have you been prescribing opioids?
A. I've been prescribing opioids since I began my medical training and my medical career in the mid-1990s. I would qualify my positive response to say that the only opioid that I prescribe now are opioids to treat opioid addiction. I treat chronic pain, but I don't prescribe

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opioids currently for the treatment of chronic pain.
Q. When you say that you only prescribe -- you prescribe opioids now only to treat opioid addiction; is that right?
A. That's correct.
Q. Is the reason you qualify it because that's a change from your past practices with respect to prescribing opioids?
A. My opioid prescribing for pain occurred mainly when I was a medical intern and not in my psychiatric practice. It's not within the scope of psychiatric practice typically to prescribe Schedule II opioids for pain.
The kind of treatment that I as a psychiatrist administer for pain has to do with psychological and mind-body interventions. I can certainly make recommendations, and I am actively involved in helping patients who have become dependent on or addicted to opioids, but I do that in collaboration with their opioid prescriber.
That is a big part of my practice now, and my medical expertise is counseling primary care doctors and pain specialists, for example, on how to safely and compassionately taper their patients down to a lower dose of a Schedule II opioid or off of an opioid.

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Q. When did you stop prescribing opioids for chronic pain?
A. In the early aughts, when I transitioned to a primary psychiatric practice.
Q. When is the last time you prescribed an opioid for pain?
A. I can't give you a specific date.
Q. Last year?
A. No, I have not prescribed opioids for chronic pain for the last 15 to 20 years of my practice.
Q. When did you last recommend that a doctor prescribe an opioid for a patient?
MR. ARBITBLIT: Object to form.
THE WITNESS: I have lots of conversations with other healthcare providers around opioids and opioid prescribing. Those are careful and nuanced conversations that are based on the evidence, that are based on my clinical experience, and on the unique situation of that patient.
Sometimes that involves recommending continuing an opioid for chronic pain at a given dose. Sometimes it involves recommending tapering to a lower dose or tapering off. It really depends on a specific patient situation.
Although I will add that much of my work has to

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do with helping healthcare providers safely and compassionately taper their patients down to safer doses or off entirely because of the harm done by taking opioids chronologically and because of the lack of evidence that opioids work for chronic pain and can even make pain worse through a process called opioid-induced hyperalgesia.

MR. MOONEY: Move to strike that answer.

Q. Dr. Lembke, my question was when did you last recommend that a doctor prescribe an opioid for a patient?

MR. ARBITBLIT: Object to form.

THE WITNESS: That is a very general question. So if you could be more specific about what opioid and what kind of clinical scenario, I would be better able to answer your question.

Q. BY MR. MOONEY: Sitting here today, you can't tell me when you last recommended that a doctor prescribe an opioid for one of your patients under any circumstances?

MR. ARBITBLIT: Object to form.

THE WITNESS: No, that's not true. That's work that I do in every clinic, and I see patients every week in clinic. So the discussion around opioids, when to prescribe, how much, whether to taper, how to taper,

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opioids and opioids in the use of chronic pain, opioids in the use of acute pain, opioids in the use of opioid use disorder is a conversation I have on a regular basis in my professional work.

Q. BY MR. MOONEY: So is it fair to say on a regular basis, you make recommendations that doctors continue to prescribe opioids for your patients?

MR. ARBITBLIT: Object to form.

THE WITNESS: As I said, I regularly have discussions about whether opioids are indicated, how to do a risk-benefit assessment, and what to do with the opioid prescription.

The -- your question implies -- I guess I would just, again, like clarification on your question because I want to make sure that I answer it accurately.

Q. You said that in your -- in your work as an addiction doctor --

A. And --

Q. As a psychiatrist.

A. And somebody who treats chronic pain and has a courtesy appointment in the Department of Pain and Anesthesia at Stanford School of Medicine.

Q. Right. You said that in the last 15 years, you personally haven't prescribed opioids for chronic pain; is that right?

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A. That's right.

Q. You said you have had conversations with other doctors on -- and provide recommendations as to whether their patients should continue to be treated with opioids?

A. Yes.

Q. When was the last time you made a recommendation that a doctor continue to prescribe patients opioids?

MR. ARBITBLIT: Object to form.

THE WITNESS: Tuesday.

Q. BY MR. MOONEY: So two days ago?

A. Yes.

Q. What pharmacy were the pills that you prescribed filled at?

A. I have these conversations around opioid prescribing and doing a risk-benefit assessment and whether the patient's developed opioid dependence or opioid addiction so often in my clinical practice and on such a regular basis that I could not tell you. It's not an isolated event in my work. So, therefore, a specific pharmacy doesn't stand out to me.

I can -- if it's helpful, I could list some of the common pharmacies in my area, but I'm not sure.

Q. Which distributors fill the prescriptions that you write?

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A. I don't know.

Q. If one of your patients told you that a pharmacy couldn't fill a prescription for opioids because the distributor wouldn't ship to that pharmacy, what would you tell your patient to do?

MR. ARBITBLIT: Object to form.

THE WITNESS: It would really depend on the specifics of that patient's circumstance.

Q. BY MR. MOONEY: If -- so what -- what would -- what would depend on the patient's circumstances?

MR. ARBITBLIT: Object to form.

THE WITNESS: The specific patient and where they got their prescription and what it was for and whether or not it was truly indicated and whether or not their report was, in fact, accurate regarding whether or not they were able to obtain that prescription for that opioid.

Q. BY MR. MOONEY: And so if one of your patients said that they couldn't fill a prescription for opioids because the distributor wouldn't ship to that pharmacy, and you went through all the circumstances of the patient and you determined that this -- this patient needed those -- those opioids, what would you tell the patient to do?

MR. ARBITBLIT: Object to form.

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THE WITNESS: Probably the first thing that I would do would be to contact the pharmacy directly and try to figure out what the circumstances were of their not having that particular medication.
Q. BY MR. MOONEY: Have you ever contacted a pharmacy to ask why they don't have a particular medication that you prescribe?
A. Frequently.
Q. And what did they -- what -- what answers have you received from pharmacies when you've made such calls?
A. Sometimes it has to do with a prior authorization. Sometimes it has to do with the fact that they don't have it in stock. Sometimes it has to do with the fact that it's at another pharmacy in their same chain and they have to have it shipped over and that will take a few days.
Sometimes it has to do with the fact that they're concerned about a pattern of behavior that they've seen in that particular patient, which makes them reluctant to dispense.
Q. Have you ever consulted with a distributor about any of the prescriptions that you've written in your practice?
A. No.
Q. Will you tell me the last pain patient you wrote a prescription for?
MR. ARBITBLIT: Object to form.
She's not going to give you specifics of her patients. That's an invasion of confidentiality.
Don't answer it.
Q. BY MR. MOONEY: Will you accept your counsel's advice?
A. That would be a violation of HIPAA for me to refer to a specific patient. I would never do that.
Q. What if I told you that I represent a distributor and I want to investigate your patients and how they're using opioids; would you then give me the name and medical records of your patient?
MR. ARBITBLIT: Object to form.
THE WITNESS: I would consult Stanford's legal and determine whether or not I was in a position to have to offer that, legally offer that information. I'm not a lawyer so I would consult a lawyer. And I would have first and foremost in my mind the care and confidentiality of my patient, which is my primary responsibility.
Q. BY MR. MOONEY: From the opioids that you've prescribed, have any been diverted?
MR. ARBITBLIT: Object to form. Assumes facts not in evidence.

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THE WITNESS: Opioids that I have prescribed have been diverted, yes.
Q. BY MR. MOONEY: And the opioids that you have prescribed that were diverted, how were they diverted?
A. They were diverted by patients to whom I gave a prescription who then either sold or gave away the medications that I prescribed to them.
Q. Did you report the diverted pills to the police?
A. No.
Q. Did you believe -- or excuse me, did you report the person who diverted the pills to the police?
A. Most of my patients suffer from addiction, and so their behavior is part of their disease of addiction, and I don't see myself in a law enforcement role. My primary obligation to my patients is to care for them while also recognizing that I have a responsibility to the public.
So when that happens, I change my prescribing to make sure that they don't have access to pills in the way that they had access before.
Q. So diversion is not a crime when it's one of your patients; is that right?
MR. ARBITBLIT: Object to form. Argumentative.
Don't answer that question.
Come up with a new one.

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Q. BY MR. MOONEY: Are you going to listen to your counsel and not answer?
A. I feel like I've answered that question.
Q. The question is pending. Can you answer the question or do you follow your counsel's advice not to answer it?
A. I'm going to follow my counsel's advice not to answer.
Q. Should doctors who know that medications they've prescribed have been diverted lose their license?
MR. ARBITBLIT: Object to form.
THE WITNESS: It really depends on the specific circumstance.
Q. BY MR. MOONEY: Do you agree that for a couple of days to a couple of weeks, opioids are magical for the treatment of pain?
MR. ARBITBLIT: Object to form.
THE WITNESS: I'm not sure I would use the term "magical." Opioids can have benefit short-term. They are a useful tool. I would never suggest that there's no role for opioids in medical treatment, but every case is unique. Opioids are very high risk, and even when prescribed short-term, it's necessary to weigh the risks against the benefits.
Q. BY MR. MOONEY: In your professional medical

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experience, if a doctor prescribes prescription opioids for short-term therapy of three weeks, how many opioid pills does the doctor prescribe?

MR. ARBITBLIT: Object to form.

THE WITNESS: It all depends on the specific circumstance on what the medical indication is.

Q. BY MR. MOONEY: Can you provide a range of the number of pills that would be prescribed in a three-week prescription?

MR. ARBITBLIT: Object to form.

THE WITNESS: I really wouldn't want to prescribe a range of pills. I don't think that's useful. I wouldn't -- every case is unique. There is such a range of medical conditions, of patient circumstances.

Q. BY MR. MOONEY: Has the number of pills in a prescription for three weeks of opioids remained the same over the past decade?

A. There is huge variation opioid prescribing across the country. In some geographic regions, opioid prescribing has decreased rapidly; in others, it has not. It really depends on which doctor.

Q. So it depends on the doctors, then?

A. It continues to depend largely on the doctor, yeah.

Q. Have you ever been to Suffolk County, New York?

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A. I have not.

Q. Have you ever practiced medicine in Suffolk County?

A. No.

Q. Have you ever been to Nassau County, New York?

A. No.

Q. Have you ever practiced -- have you ever been licensed to practice medicine in the State of New York?

A. No.

MR. MOONEY: We've been going about an hour. Do you want to take a break?

MR. ARBITBLIT: Sure.

THE VIDEOGRAPHER: Going off the record, the time is 9:03 a.m.

(Recess.)

THE VIDEOGRAPHER: Back on the record. The time is 9:26 a.m.

Q. BY MR. MOONEY: Dr. Lembke, all in, how much have you been paid by plaintiffs in any opioid litigation in this country?

MR. ARBITBLIT: I'll object and instruct not to answer unless we get an agreement that this is reciprocal.

Q. BY MR. MOONEY: Will you follow your counsel's instruction?

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A. Yes, I will.

Q. Last year, what percentage of your total compensation came from serving as an expert in opioid litigation in the United States?

A. I don't know. I haven't made that calculation.

Q. Have any of the plaintiffs in an opioid litigation allowed you to fly on their private plane to attend any hearing?

A. No.

Q. You said you've been paid approximately $20,000 so far for the New York litigation; is that right?

MR. ARBITBLIT: Object to form.

THE WITNESS: Again, I haven't added it up so I don't know.

Q. BY MR. MOONEY: How many hours have you spent working on the New York litigation?

A. I haven't added it up. I don't know.

Q. We were talking a little bit earlier about a efficient supply chain. Strike that.

Can you approximate how long you've spent working on the New York litigation?

A. I'm reluctant to approximate because I really don't know. I would really -- I have a record. I could add it up, but I -- I don't want to approximate and then be far afield from what it actually was.

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Q. So sitting here today, you can't provide an approximation of how much time you've spent; correct?

A. I can easily provide the exact number if you'd like me to access those records. I kept very careful documentation of the time that I spent.

Q. Did you bring that time with you today?

A. I did not.

Q. So sitting here today, you cannot approximate how much time you've spent on the New York litigation?

A. That's correct.

Q. We talked about an efficient supply chain earlier. Do you recall that conversation?

A. Yes.

Q. Is Amazon an efficient distribution supply chain?

MR. ARBITBLIT: Object to form.

THE WITNESS: I'd like to know how that question is relevant.

Q. BY MR. MOONEY: That's not -- that's not a question that you get to ask. I asked a question. Do you have an answer?

MR. ARBITBLIT: Object to form.

Q. BY MR. MOONEY: Do you consider Amazon to be an efficient distribution supply chain?

MR. ARBITBLIT: Object to form.

THE WITNESS: It does seem efficient.
Q. BY MR. MOONEY: Can you identify any public statement that you made before April 2015 in which you claimed prescription opioids were overprescribed?
A. Yes.
Q. When did you make that statement?
A. I published a New England Journal of Medicine perspective on the opioid crisis.
Q. And when did you publish that perspective?
A. That was in 2012.
Q. And in that perspective, you said that prescription opioids were overprescribed?
A. Yes, I did.
Q. Can you identify any earlier statements than the 2012 Journal of -- New England Journal of Medicine perspective?
A. Prior to 2015, I was actively writing my book Drug Dealer M.D., How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop, and I was also teaching on the topic of the opioid problem and giving lectures. So I was frequently making statements regarding the oversupply and overprescribing of opioids.
Q. Can you identify any statements earlier than 2012 in which you said that prescription opioids were overprescribed?

A. Do you mean written statements, published statements, or just statements in general?
Q. Let's start with published statements and then we can turn to written statements or journal articles, rather than any talks or lectures. Not for your students, but public facing.
MR. ARBITBLIT: Object to form.
THE WITNESS: Let me take a look at my CV which is in my report.
It's possible that I referred to the oversupply of opioids in the chapter that I wrote for the Stanford School of Medicine Handbook of Developmental Psychiatry On Adolescents and Young Adult Substance Use Problems. I'd have to refer to that document to verify that.
Q. My question was about overprescribing, not oversupply.
A. It's possible that I referred to it in that document. I'd have to go back and reference that.
It's possible that I made a reference to overprescribing of opioids in a publication for addiction in 2013, From Self-Medication to Intoxication, Time For a Paradigm Shift.
As I said, in 2012 in the New England Journal of Medicine piece, Why Doctors Prescribe Opioids to Known Opioid Abusers.

So, you know, I've been working and studying this problem since the early aughts so it's probable that I made statements to the overprescribing of opioids prior to 2012. But 2012 was a kind of a landmark paper that I published in the New England Journal of Medicine on this topic followed by many publications since then regarding the overprescribing and the oversupply of opioids.
Q. You reference on page 13 of your report in romanette II a 1954 study. And you quote the study as saying: "Morphine is not the answer to chronic pain."
Do you recall that study?
A. Yes, I do.
Q. Can you identify any article that you wrote between 1996 and the present in which you cited that 1954 study?
A. No.
Q. In your report you write about a 2001 continuing medication -- or continuing medical education course on the treatment of pain that every licensed physician in California was required to attend.
Do you recall that continuing medical education course?
A. Yes, I do.
Q. So first off, what is a continuing medical education course?

A. Continuing medical education is courses that are required for physicians to take after they finish medical school and after they finish residency, once they're in practice, in order to ensure that they have the latest evidence to inform their care of patients. Attending a certain number of continuing medical education courses per year is mandatory in order to maintain licensure.
Q. And continuing medical education courses, are they sometimes called CMEs?
A. Yes, they are.
Q. Did you attend the 2001 CME on the treatment of pain that every licensed physician in California was required to attend?
A. Yes, I did.
Q. Where was that CME held?
A. That was held in Palo Alto, California.
Q. And how many people attended that event?
A. I don't know the exact number. It looks to be in the thousands.
Q. And who presented at that 2001 CME?
A. I don't recall specific presenters except for some of my Stanford colleagues who presented at that CME.
Q. Were there any representatives from a pharmaceutical distributor that presented at the 2001 CME?

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A. There probably were, but I don't recall any specifics.
Q. Why do you say there probably were?
A. Because it is very common for the pharmaceutical industry to financially support CME and also to have booths or tables at these events to promote their products. That's been the standard, unfortunately.
Q. My question was different. Were there any representatives of a pharmaceutical distributor, not the pharmaceutical industry, the pharmaceutical distributor, that presented at the 2001 CME?
A. Not that I recall.
Q. You write in your report, page 23, paragraph romanette V: "I recall that there was no accurate presentation of the risks of opioids, and the messages that were provided tracks the misconceptions described above regarding overstatement of the benefits of opioids."
Did I read that correctly?
A. Yes, you did.
Q. At the time you attended the CME in 2001, did you do anything to alert the attendees of the event that the information that was being provided that day was inaccurate?
A. I was extremely early in my career. I was very

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junior in my institution, and I did not alert anybody because at that time, I myself was buying into those misrepresentations. I was the convinced or let's say partially convinced recipient of those misleading messages.
Q. Any time in the year after the 2001 CME, did you do anything to alert doctors that you believed the information that was provided about prescription opioids was inaccurate?
A. The evolution in my thinking occurred over that decade, from approximately the year 2000 or, let's say, the late -- mid-to-late '90s. I was trained in -- I went to medical school, as you know, in the 1990s, my residency in the late 1990s, and the evolution in my thinking occurred over that decade since my medical training.
So I did not alert anybody because I was experiencing an evolution in my own thinking, and a growing concern and skepticism regarding the messaging that I had been the recipient of in medical school, in residency, and at continuing medical education courses.
And as I read more in the literature and saw patients, I began to realize that what I had been taught was false.
Q. Coming back to the question. At any time in the

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year after 2001, did you do anything to alert doctors that you believed the information that was provided at the 2001 CME about prescription opioids was inaccurate?
A. Yes, I did.
Q. What did you do?
A. I began in my lectures to medical students and residents and colleagues to talk about the problem of opioids, the fact that they were being overprescribed, that we, as a healthcare community, had been sold a bill of goods regarding their safety and efficacy, and that we had a responsibility to our patients to do something about that problem.
I -- and I also, as you know, then published an article in 2012 in The New England Journal of Medicine which directly addressed this problem, and some of the origins, though not all of the origins, specifically in order to alert my colleagues in the healthcare profession about the problem of opioid overprescribing and the inherent risks associated with it.
And then I also began work on my book that was ultimately published by Johns Hopkins University Press in 2016 that specifically addresses this opioid crisis.
My intention in writing the book was to educate my colleagues and patient-consumers about this problem.
Q. Let's try this one more time.

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In the year after the 2001 CME, 2001 to 2002, did you do anything to alert doctors that you believed the information that was provided about prescription opioids was inaccurate?
A. I probably did. Informally talking about with colleagues, expressing my skepticism and concern, but again, that was my beginning of my awareness of a problem as I began seeing more and more patients who were misusing, dependent on, and addicted to prescription opioids.
So to answer your question, it wasn't something that happened suddenly overnight. It was an evolution in my thinking beginning in the late 1990s, early aughts. So there's not a specific point, but as I became concerned, yes, I regularly talked with colleagues. I began to think about the problem and address the problem.
Q. Was the CME presented again in 2002 with similar misinformation?
A. I don't know.
Q. What about in 2003?
A. I didn't track that exact CME and whether it was presented, but I know that it was a requirement in 2001 to complete a CME on pain, which was a very unusual circumstance. There were very few mandatory CMEs across all specialties.

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And so it was significant to me, even at the time that I took the 2001 CME, that I was being mandated as a psychiatrist to take a course on pain.

What I learned, through my work and my research over the ensuing decade, is that even that requirement was probably the result of the opioid pharmaceutical industry and their lobbying efforts to create this paradigm shift in the treatment of pain and to disseminate their misleading messages to every kind of medical specialist.

Q. Who required -- where did the -- where did the requirement come from that doctors had to attend this 2001 CME?

A. It came from the California State Medical Board.

Q. Exhibit B to your report lists the materials you considered in reaching your opinions in this litigation; is that right?

A. Yes.

Q. And you tried to make sure that that list was complete?

A. Yes, I did.

Q. It was missing a few documents; right?

A. Which documents are you referring to?

Q. Well, last night your counsel provided us with a supplemental list of materials you considered.

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Are you aware of that?

A. Yes.

MR. MOONEY: Okay. Handing you Exhibit 3 to your report.

(Exhibit 3, Supplemental Materials Considered List, Dr. Anna Lembke, marked for identification.)

Q. BY MR. MOONEY: Which is the list of supplemental materials considered that we received from counsel last evening.

Have you identified any other documents between last night and this morning that should be on a list of -- or a list of materials you considered in forming your opinion?

A. No.

Q. And so if you considered a document in forming your opinions that you offer in this case, you listed the document on Exhibit B or the supplemental list that was provided last night; correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: My opinion has been informed by the documents that I've reviewed as well as 20 years of clinical experience and training.

Q. BY MR. MOONEY: Right. If there are materials, though -- setting aside your clinical training and your

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clinical experience -- if there are materials that you considered in forming the opinions that are in your report, you listed them in Exhibit B or in the supplemental materials considered list; is that correct?

A. To the best of my knowledge, that is correct.

Q. Did you consider any documents that were produced by a distributor in this case?

A. I don't believe so. Except for the McKesson Nucynta coupons, which I believe were created by McKesson. Or at least by McKesson in collaboration with Janssen.

Q. When you use the term "pharmaceutical opioid industry" in your report, are you using it to mean the same thing you meant in the Federal litigation report?

A. I'm using it to mean opioid manufacturers, distributors and pharmacies.

Q. And so are you meaning -- are you using it to mean the same thing that you meant in your Federal litigation report?

A. Yes.

Q. On page 6 of your report, at Opinion 3 you write: "The pharmaceutical opioid industry contributed to the paradigm shift in opioid prescribing through promotional materials and its use and manipulation of key opinion leaders, continuing medical education courses,

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professional medical societies, a Federation of State Medical Boards to the Joint Commission to convey misleading messages about the safety and efficacy of prescription opioids."

Did I read that correctly?

A. Yes, you did.

Q. What is a "key opinion leader"?

A. A key opinion leader is an individual with influence in the medical community, often an academic of prestigious standing, for example, a professor or a clinic chief at a major university or medical center who is then working as a paid consultant for a pharmaceutical company to promote their messaging.

Q. Can you identify any payments to a key opinion leader by CardinalHealth?

A. No.

Q. How about for McKesson?

A. No.

Q. Same question for AmerisourceBergen Drug Corporation and Rochester Drug Co-op.

A. No.

Q. When you say "the pharmaceutical opioid industry used and manipulated key opinion leaders," are you talking about distributors?

A. I'm talking about opioid manufacturers.

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Q. When you say "the pharmaceutical opioid industry used and manipulated continuing medical education courses," are you talking about distributors?
A. No.
Q. When you say "the pharmaceutical opioid industry used and manipulated professional medical societies," are you talking about distributors?
A. No.
Q. When you say "the pharmaceutical opioid industry used and manipulated the Federation of State Medical Boards and the Joint Commission," are you talking about distributors?
A. No.
Q. Can you identify any false or misleading claim about opioids that was made by a pharmaceutical distributor that has been named as a defendant in this case?
A. No.
Q. Of the oxycodone and hydrocodone pills dispensed in the United States, what percentage were prescribed by a doctor and filled by a patient?
MR. ARBITBLIT: Object to form.
THE WITNESS: I refer to my report, page 12, the NASEM report, based on DEA reports noting 76 billion oxycodone and hydrocodone pills delivered in the

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United States, with 12 to 19 billion pills diverted. Diversion can occur at multiple levels prior to a doctor prescribing it or a pharmacy receiving it, at the time of prescription and also after the prescription. So it's extremely hard to estimate.
MR. MOONEY: Move to strike.
Q. But what percentage of -- of the oxycodone and hydrocodone pills dispensed in the United States, what percentage were prescribed by a doctor and filled by a patient?
MR. ARBITBLIT: Object to form.
THE WITNESS: The majority, but I don't know the exact percent.
Q. BY MR. MOONEY: And of the percentage of opioids that are prescribed by a doctor and filled by a patient, what percentage of those pills were pursuant to illegal prescriptions?
MR. ARBITBLIT: Object to form.
THE WITNESS: Very hard to quantify that. It would really depend on what you mean by an illegal prescription.
Q. BY MR. MOONEY: What percentage of doctors' prescriptions for opioids are not for legitimate medical purposes?
A. Again, I think that the question doesn't really

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appreciate the complexity of the problem. Patients who receive a prescription for a legitimate medical purpose can go on themselves to be addicted to that opioid. They can also divert a portion of their legitimate prescription to others who are then harmed.
That diversion may occur intentionally or unintentionally, for example, a teenager getting pills from a grandparent's medicine cabinet without the awareness of that individual who has the legitimate prescription.
Then there are individuals who intentionally seek out a doctor for the purpose of obtaining pills for non-legitimate medical purposes.
So it's very difficult to answer that question simply. It's a complicated question. It's a complicated situation, and I don't think we even now fully know accurately of the rates of diversion. We have estimates, but...
Q. I understand that diversion can occur after the prescription is filled and it can occur in other places, too.
My question is: What percentage of doctors' prescription of opioids are not for legitimate medical purposes?
MR. ARBITBLIT: Object to form.

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THE WITNESS: How would you define "legitimate medical purposes"?
Q. BY MR. MOONEY: As a doctor, do you have responsibilities to ensure that your patients -- or that you prescribe medications for patients that are for legitimate medical purposes?
A. Yes, we do. But if we've been misinformed about what a legitimate medical purpose is, then we may prescribe believing that we're engaging in a legitimate prescription, when in fact, that prescription may not be what is helpful to that patient.
Q. What percentage of doctors' prescriptions for prescription opioids are for a legitimate medical purpose, assuming that it is done with the belief that they are engaging in appropriate medical care?
MR. ARBITBLIT: Object to form.
THE WITNESS: The majority of opioid prescriptions are for a legitimate medical purpose, but I couldn't quantify it. I just believe that the majority of doctors are well-intended and trying to help their patients.
There are doctors who have lost their moral compass and are prescribing opioids knowing that their patient shouldn't get those opioids, and that subset is a part of this problem, but another large part of this

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problem is well-intended doctors who believe they are prescribing opioids for legitimate purposes but have been misinformed and miseducated due to defendants' actions.

Q. What percentage of opioid medication prescribed by a doctor and dispensed by a pharmacy sits unused in a patient's medicine cabinet?

MR. ARBITBLIT: Object to form.

THE WITNESS: There are data coming out now showing that a large percentage of opioids that are prescribed by a doctor are not, in fact, used by the patient, especially in the postoperative setting. These are data that are now being used to inform how opioids should be prescribed postoperatively.

What the studies are showing -- and I do cite them in my report, and I can go to that place, if you'd like -- are that as healthcare providers are cutting back on opioid prescriptions, they're finding that their patients are reporting no increases in pain, no increases in calls for refills, and that they have fewer opioids left sitting around in medicine cabinets for teenagers or neighbors or whoever it is to come and take those opioids. So --

Q. BY MR. MOONEY: Do you -- sorry. Go ahead.

A. So my point being that with the growing awareness of the opioid epidemic and research that is

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studying the extent of the harm, we are finding out that a lot of patients are using some of their prescription and leaving the rest to either be stolen, or in some cases, they themselves may be diverting part of their prescription or selling part of their prescription.

Q. And when did that growing awareness begin?

MR. ARBITBLIT: Object to form.

THE WITNESS: That growing awareness on my part?

Q. BY MR. MOONEY: Sorry. Go ahead.

A. That began for me in the early 2000s, as I started seeing more and more patients coming into my office reporting that they were misusing or addicted to opioids. When I asked them where they got those opioids, many of them reported that they got the opioids from a doctor.

Many of them actually believed that they were taking the opioids in part for a legitimate pain condition but also expressed concern that they were becoming addicted through that legitimate prescription.

I also began seeing more and more patients in the early aughts and beyond reporting that they had increased easy access to prescription opioids from friends and family members, left over opioids in medicine cabinets.

I had teenagers coming in saying they were

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getting opioid pills from their friends at school, leftover prescriptions or from somebody at school who had pills who sold or gave it to them.

So what I saw over the first several decades of this century was a growing number of patients who were telling me that opioids were everywhere, that they were easy to get, that you could ask a friend or you could find a dealer, you know, one text message away, or you could go see a doctor and easily obtain them.

Again, some of these were individuals who were intentionally seeking out opioids for recreational use and other of them were pain patients who themselves were becoming addicted through their legitimate prescription.

I've also spent much of the last five years traveling around the country, all over the country, talking to doctors, trying to educate them about this problem, urging them to prescribe opioids more judiciously. And in that process, I've had many conversations with doctors who have expressed that they were duped by the pharmaceutical industry, that they engaged in a very liberal prescription pad in terms of prescribing opioids, and that they were looking back on that practice with regret.

Interestingly, I was in Buffalo last year to give a conference, to give a talk on the opioid epidemic

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to doctors, and one of the doctors came up to me afterward and said that in her clinic, which was a clinic for gynecologic cancer -- she had been in practice more than 15 years -- they had instituted a new policy of getting urine drug screens in their long-time opioid chronic pain patients.

And to her shock and dismay, they discovered that a large percentage of those patients had a urine drug screen that was negative for opioids, the implication being that individuals to whom they had been giving what they thought were legitimate prescriptions for many years, that those individuals were not, in fact, taking the opioids that they were prescribing.

So through these many types of conversations, my own clinical experience, and my reading in the literature, I have seen what I have called in my report the tsunami effect, the rising tide, the increased supply.

And as an addiction medicine specialist, I know that one of the biggest risk factors for developing addiction is access to the drug. If you live in a neighborhood where drugs are sold on the street corner, you're more likely to try that drug and you're more likely to get addicted to that drug.

We've been living in a society for the past

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30 years where opioids are readily available to anybody who wants them. And as a direct result of that increased supply and exposure, we now have an opioid epidemic of addiction and death on our hands.

Q. Dr. Lembke, do you have Exhibit 1 in front of you?

A. Exhibit 1.

Q. It might be under your report. The copy that I used --

A. This?

Q. No, the Court's order.

A. Yes, I do.

Q. Okay. Now, were you made aware of this Court order before your deposition today?

A. Yes, I was.

Q. And so you know that Justice Garguilo entered an order that said in paragraph 1: "Your role as an expert is not one of advocacy. Your role is to listen to the question and answer the question. You are not to comment on anything beyond the information sought within the question."

Did I read that correctly?

A. Yes, you did.

Q. Now, before you started answering my question -- the question that was pending before your monologue:

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"When did that growing awareness begin?" That's a time question, is it not?

A. (Nods head.)

MR. ARBITBLIT: Object to form.

THE WITNESS: Because my growing awareness as implied by the word "growing," growing is something that happens gradually over time. Things don't grow in a second or a day, I felt that in order to accurately answer your question, I needed to explain the growth of my awareness over the time period during which it occurred.

Q. BY MR. MOONEY: The information sought within the question, "When did it begin," you said, "It began for me in the early 2000s." That's an answer to when; correct?

A. It is a partial answer to when. If one's growing awareness -- and those were your words, "growing awareness," a growing awareness occurs over a longer period of time, or at least my growing awareness occurred over a longer period of time. And my response was my best effort to thoroughly and accurately answer your question.

MR. MOONEY: All right. We have a limited amount of time with you so I'm not going to argue with you on this any more, but I move to strike everything

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after "in the early 2000s."

Q. For the medical community at large, when did the growing awareness of the opioid epidemic begin?

MR. ARBITBLIT: Object to form.

THE WITNESS: In 2011, the CDC issued a warning that we were in the midst of a prescription drug epidemic, and they, in their warning, clearly stated that the case was increased prescribing of opioids and other psychotropic medication.

I think that that was a very important missive and an important year that contributed to a growing public awareness around the opioid epidemic.

Following that, there were increasing numbers of reports in the media and in the lay press that I think also helped the growing awareness, the public awareness.

I can say that approximately two years ago, for the first time in my professional career, I started seeing chronic pain patients coming in asking for help to get off of their opioids, that they had heard that opioids were dangerous, that they had been on them for a long time, and that they wanted to get off.

That, to me, was evidence of the slow shift and a growing awareness, when patients themselves were coming in saying, I read this article in the newspaper, or I heard this on the radio that opioids are dangerous and I

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didn't know that, and I'd like to get off.

Q. BY MR. MOONEY: Do you have an opinion on the steps distributors could take to prevent unused medicine from doctors' prescriptions from sitting unused in people's medicine cabinets?

MR. ARBITBLIT: Object to form.

THE WITNESS: I think that anything the opioid pharmaceutical industry can do to limit the supply of opioids to just what is evidence-based use of those opioids would help reduce the number of pills sitting in people's medicine cabinets.

Q. BY MR. MOONEY: If distributors provided 20 percent less opioids across the board to all pharmacies and hospitals, would that help with the epidemic?

MR. ARBITBLIT: Object to form.

THE WITNESS: I'm not in a position to opine on exact percentages or numbers. There are other experts who will be weighing in on the -- on the role of distributors who possibly could answer that, but that's not a question that -- that I'm in a position to answer.

Q. BY MR. MOONEY: How would a pharm- -- if distributors provided 20 percent less medication across the board to pharmacies and hospitals, how would those pharmacies and hospitals decide which patients'

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prescriptions to fill and which ones should not be filled?
MR. ARBITBLIT: Object to form.
THE WITNESS: The question is a hypothetical. I am uncomfortable with a specific number of 20 percent. But I would say that the bottom line is that pharmacies and hospitals should fill prescriptions that are based on evidence-based medicine, with careful scrutiny as to whether or not the individual and the community is being harmed by the way in which those prescriptions are being filled. So everybody has responsibility.
Q. BY MR. MOONEY: Including doctors?
A. Including doctors, yes.
Q. What would you -- what would a pharmacist need to know to determine which prescriptions to fill and which ones should not be filled?
MR. ARBITBLIT: Object to form.
THE WITNESS: Even now, pharmacists are checking the prescription drug monitoring database to see if the patient is engaged in so-called doctor shopping or whether or not there's dangerous co-prescribing, such as combing opioids and benzodiazepines or opioids and other sedatives.
A pharmacist should also have some familiarity with that doctor and their general practice and whether

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or not they are practicing in a responsible way.
The pharmacist should also be aware of the CDC guidelines that are recommending that opioids not be used as first-line treatment for pain and that doses for acute pain be limited.
Pharmacists should also just have good old common sense, and if they're observing somebody who is clearly impaired or intoxicated, along the lines of somebody who may be misusing or addicted to opioids, that should also play into their decision making.
For example, I have had pharmacists call me, and even though I wrote a legitimate prescription for what I believed was a legitimate medical indication, they have called me and said, you know, I'm concerned about this patient, she's presenting in a way that makes me think she's intoxicated, and she's getting prescriptions, multiple prescriptions from, you know, other providers. Also, I have this history with this particular patient prior to her being your patient, and so I know that she has had X, Y or Z problem.
These are all emergent, relevant, health-related details that need to be communicated between everybody in the opioid supply chain.
Q. BY MR. MOONEY: In what way did prescription opioid distribution campaigns impact prescribing rates in

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Nassau or Suffolk County?
A. By shipping large numbers of pills very efficiently so that pharmacies were heavily stocked with these pills, Suffolk County, along with the rest of the United States, was heavily impacted.
Q. Right. My question, though, is: How did the distribution campaign affect the rates at which doctors prescribed opioids in Nassau and Suffolk County?
A. I refer to this in my report. I'd like to go to that spot.
Okay. So between -- as I say on page 89 of my report: "New York State data show a four-fold increase in opioid mortality in the 25 to 44 age group from 2010 to 2016." And that includes Suffolk County.
So that increase in addiction among young adults is a result of the increased supply of opioids in that community, and the increased supply is a result of defendants' actions, including distributors and pharmacies.
MR. MOONEY: Move to strike.
Q. Dr. Lembke, my question was: In what way did the distribution campaigns impact the rates at which doctors prescribe opioids in Nassau and Suffolk County?
A. Let me give you a corollary example. I saw a patient last week with alcohol abuse disorder, and I

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prescribed Antabuse disulfiram to him, and he was not able to obtain that medication from several different pharmacies in the area. I'm not sure why. So, therefore, we thought about a different or alternative medication.
So if I'm practicing in a region where every single opioid formulation under the sun is readily available at every single pharmacy, and that becomes the normative way to address pain, that is -- this is an example of how distributors have impacted the rates at which doctors describe opioids.
Q. What percentage of prescriptions for opioids are due to a doctor's decision to provide a different or alternative medication because the medication that they want to provide is not available?
MR. ARBITBLIT: Object to form.
THE WITNESS: I guess I don't really understand the question.
Q. BY MR. MOONEY: Well, I didn't understand your answer before because I asked about Nassau and Suffolk County.
But what I understood you to mean was when you thought about prescribing a different or alternative medication that wasn't available, you thought about providing something else; right?

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A. (Nods head.)
Q. And then you said: "If I am practicing in a region where every single opioid formulation under the sun is ready available" -- "readily available at every single pharmacy, and that becomes the normative way to address pain, that is an example of how distributors have impacted the rates at which doctors prescribe opioids."
Is that the gist of what you said?
A. Yes.
Q. So my question is: Taking your corollary example about an alcohol -- a patient suffering from alcoholism in California, what percentage of prescriptions are written for opioids in Nassau or Suffolk County because the doctor wasn't able to get the other drug that he or she wanted because it was unavailable at the pharmacy?
A. I don't --
MR. ARBITBLIT: Object to form.
THE WITNESS: I don't know.
Q. BY MR. MOONEY: Are you offering on opinion on the appropriate number of pills that should have been distributed in the State of New York?
A. No.
Q. You've talked a couple of times about the NASEM report on page 12 of your report.

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A. (Nods head.)
Q. And you referenced in romanette III that there are several ways that prescription drugs are diverted to non-medical use.
Do you recall writing that in your report?
A. Yes.
Q. And the first example you give is diversion before a prescription has been filled, for example, theft from production facilities or retail pharmacies; is that right?
A. That's right.
Q. Are you offering any opinion about any theft from a distributor in this case?
A. No.
Q. What percentage of diverted opioids are due to theft from a distributor?
A. I don't know.
Q. Can we agree that actual -- can we agree that actual theft is rare?
A. I wouldn't agree to that because I have nothing to base that on.
Q. The second version -- the second form of diversion in your report that you reference is diversion via filling a prescription, for example, pursuant to doctor shopping and high-frequency prescribers; is that

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right?
A. Yes.
Q. And the third one is diversion after the prescription has been filled, for example, by subsequent transfer or sale to a third party; is that right?
A. Yes. Yes, that's right.
Q. Do you agree that after a prescription for an opioid has been filled, a pharmaceutical distributor no longer has control over what happens to those dispensed drugs?
MR. ARBITBLIT: Object to form.
THE WITNESS: I think that a distributor has responsibility regarding the diversion of an opioid pill after it's been filled.
Q. BY MR. MOONEY: My question was different: After the pharmaceutical opioid has been dispensed --
A. Uh-huh.
Q. -- do you agree that the distributor no longer has control over what happens to the drugs?
MR. ARBITBLIT: Object to form.
THE WITNESS: What do you mean by "control"?
Q. BY MR. MOONEY: After one of your patients fills a prescription for opioids, can CardinalHealth go to their house and take the unused medication out of their closet?

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MR. ARBITBLIT: Object to form.
THE WITNESS: No, but what CardinalHealth can do is note suspicious orders or regions in which there is a heavy volume of pills not justified by the need for analgesia in that community and investigate.
MR. MOONEY: Move to strike everything after "no."
Q. Do you have a basis to offer an expert opinion in this case that pharmaceutical distributors have the ability to control what happens to prescription opioids after they have been dispensed pursuant to a doctor's prescription?
A. Again, I think I answered that. I think those things are tied. I think a distributor has a responsibility to track what happens to the prescription after it's been dispensed, and in the case of finding a suspicious or concerning situation, to intervene.
Q. In your own medical practice, have you ever reported to a distributor which medications you've prescribed and to whom?
A. No.
Q. Why not?
A. That's just not something I've ever done.
Q. Why not?
A. For the most part, I track my patients and their

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use of the opioids that I prescribe extremely closely, such that if there is diversion of any sort, it's very minimal. I catch it within the week because of the way that I practice, and so I'm able to take care of that situation.

And that is not, by the way, the standard of care or it has not been the standard of care. We're trying to change that. That's not the way that opioids are commonly being prescribed and monitored.

Q. Of the three types of diversion that you list in romanette III on page 12, only one diversion before the prescription is filled can occur when a distributor is in physical possession of the prescription opioids; is that right?

A. Yes.

MR. MOONEY: Let's take like a 15-minute break and I will...

MR. ARBITBLIT: Thank you.

THE WITNESS: Thank you.

THE VIDEOGRAPHER: Going off the record, the time is 10:19 a.m.

(Recess.)

THE VIDEOGRAPHER: Back on the record, the time is 10:37 a.m.

Q. BY MR. MOONEY: Dr. Lembke, before the break,

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you testified that a distributor has a responsibility to track what happens to the prescription after it's been dispensed, and in the case of finding a suspicious or concerning situation, to intervene.

Was that your testimony?

A. Yes.

Q. How is a distributor supposed to track an individual prescription?

A. There are other experts who will be testifying on the legal responsibilities of distributors. That's not my role here. But my opinion is that everybody in the opioid supply chain has a responsibility, and the unique responsibility of distributors is to scrutinize and identify suspicious orders or an area of the country or a pharmacy where it appears that the supply of opioids is increasing beyond medical need.

Q. You also said, though, before the break that a distributor has a responsibility to track what happens to the prescription after it has been dispensed. My question is: How do they do that?

A. I -- I can suggest ways that -- that they might do that. I think that's maybe more appropriate for abatement.

Again, the scope of my expert testimony is really about the impact of increased supply on the rates

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of addiction and overdose death, and the specifics of the distributors responsibility from a legal perspective is something that other experts will opine on.

Q. So you don't have a proposal in your report as to how a distributor is supposed to track individual prescriptions after they've been dispensed; is that correct?

A. That's correct.

Q. You said that you've never provided prescription information to a distributor. Have any of your colleagues at Stanford?

MR. ARBITBLIT: Object to form.

THE WITNESS: I don't know.

Q. BY MR. MOONEY: You also said before the break that you generally catch diversion within a week; is that right?

A. That's right.

Q. How do you do that?

A. We have a very high level of scrutiny and stewardship in our clinic, informed by my awareness of this problem and my understanding of the disease of addiction. So we dispense opioids on a weekly basis, and patients come in every week, and we check the prescription drug monitoring database in order to ensure that they're not going to other prescribers to get the

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same or similar prescription or engaging in dangerous co-prescribing that we weren't previously aware of.

We also get urine drug screens at every visit early in our opioid prescribing relationship and then at random intervals later, in order to ensure that the patient is taking the opioid that we are prescribing to them and is not taking other substances that are prohibited through our patient-provider contract.

We have a patient-provider contract that we discuss what is -- what the patient's responsibilities are, what the provider's responsibilities are.

We also actively engage family members to gather collateral information. We regularly check the electronic medical record to see what other types of treatments or co-occurring medical problems the patient may have received or is receiving.

So we have a very high level of scrutiny, informed by regular monitoring, which, by the way, was not the way that I was educated in medical school and training. That's something that I have implemented in my practice over time in recognition of the fact that patients can at any point deviate from taking their opioid as prescribed because of the overwhelming pull of opioid medications and the vulnerability that we all have to misuse or become addicted to these medications.

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Q. So the high level of scrutiny that you have implemented in your practice, do you consider those to be best practices?
A. I do, yeah.
Q. And are those best practices practices that are followed in the State of New York?
MR. ARBITBLIT: Object to form.
THE WITNESS: I would say in general across the country, including New York, that those have not been standard practices, primarily because defendants created a climate in which opioids were considered effective, safe, and in which we were taught that the risk of addiction through a doctor's prescription is very rare, less than 1 percent.
And because of that, doctors came to believe and were educated to believe that they have -- they could have very low levels of scrutiny, as long as they were prescribing for a patient with a legitimate pain condition, as if that conferred some kind of immunity to the problems related to opioids.
A lot of my work is trying to implement the best practices akin to what we do in our clinic and which other clinics are doing now as well, as I alluded to earlier in my conversation with the gynecologist in Buffalo, New York. But it will take an infusion of

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resources to provide the education and training and medical infrastructure to implement best practices.
Q. BY MR. MOONEY: When you catch diversion, do you alert authorities?
MR. ARBITBLIT: Object to form.
THE WITNESS: Our scrutiny is so close that when I catch diversion in my patients -- and again, it's not even that I have a certainty about diversion. Patients will seldom, if ever, admit to diversion. But a way that I might suspect division is, for example, I do a urine drug screen and the urine drug screen does not detect the opioid that I'm prescribing. And then I'm very worried that the patient is diverting that opioid.
Then I will have an informed discussion with them, where I tell them about my concerns. Typically the patient will deny because that's the nature of the beast.
And then we will make modifications in the care so that I can more closely steward that medication until I have a level of certainty that the pill is not being diverted.
If I can't obtain that level of certainty, then I -- I don't prescribe that medication any longer. I try to find some kind of alternative treatment.
Q. BY MR. MOONEY: When you confirm diversion, do you alert legal authorities to that diversion?

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MR. ARBITBLIT: Object to form.
THE WITNESS: I have not in my clinical experience encountered diversion with such certainty that I felt it was necessary to alert legal authorities. I've had suspicion for diversion and have acted on those suspicions.
Q. BY MR. MOONEY: So when you find something suspicious but can't confirm that it's suspicious, your practice is to not report that suspected diversion; is that right?
A. That's right, because sometimes my suspicions are unfounded. So, for example, the urine drug screen has a certain sensitivity and specificity which is not 100 percent accurate or, you know, maybe the patient missed their dose for a legitimate reason, which they then explained to me.
So a negative urine drug screen is evidence of them not taking the medicine, but not because they're diverting it, but because they forgot or they lost their pills or what have you.
So, you know, I have to gather as much evidence as I can to make an informed clinical judgment, but as soon as there's evidence of any kind of suspiciousness, I act on that immediately. I discuss it with the patient, I discuss it with their family members, I express the

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concern to my patient, and I change my prescribing.
MR. MOONEY: Move to strike everything after "that's right."
Q. Dr. Lembke, the question was: When you find something suspicious but can't confirm that it's -- can't confirm it's suspicious, your practice is to not report that suspected diversion.
MR. ARBITBLIT: Object to form.
Q. BY MR. MOONEY: Is that right?
A. When I find something that's suspicious, my practice is to report it to the patient, to report it to concerned family members, to report it to my interdisciplinary treatment team, to report it to the dispensing pharmacist. That is my standard practice.
I do not go to legal authorities because I have never had occasion in which I was so convinced about diversion that harmed -- that had the potential to harm a large number of people, and I felt that I could contain my -- what -- what -- what might be diversion within my clinic by immediately changing my prescribing or my intervention around that patient.
Q. What threshold would you look for to be convinced about diversion and harm that you would feel the need to report it?
MR. ARBITBLIT: Object to form.

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THE WITNESS: It would depend on the circumstances. These are judgment calls. But if I saw a consistent repeated pattern of pills that I was prescribing not being taken by my patient and ending up with somebody else, I would report it.

Q. BY MR. MOONEY: You never called the police to report diversion from your patients?

A. I am remembering a situation in which I was discussing with police a case of diversion, but I don't remember if I initiated the call or if somebody else did.

Q. Have you ever called the DEA to report diversion from your patients?

A. No.

Q. Who is the last patient of yours who you had suspicions was diverting opioids?

MR. ARBITBLIT: Object to form and invades confidentiality.

THE WITNESS: Yeah, I can't talk about a specific patient scenario.

Q. BY MR. MOONEY: What condition did the patient have?

A. The patient had opioid use disorder, opioid addiction.

Q. And was that patient with opioid use disorder being prescribed opioids?

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A. Yes.

Q. Does every state have a medical board?

A. To my knowledge, yes.

Q. What's the New York medical board called?

A. New York State Medical Board.

Q. That's what it's called?

A. I believe so, yes.

Q. Is it true that doctors who -- or excuse me, does the New York -- strike that. My microphone fell.

Does the New York Board of Medicine license doctors?

A. Yes, I believe so. I believe they're a licensing body as well as a monitoring organization.

Q. Does the State of New York also license doctors who describe pain medications to prescribe those medications?

MR. ARBITBLIT: Object to form.

THE WITNESS: There are multiple different organizations involved in physician licensure. So the State Board is -- is one of those, but when it comes specifically to prescribing, the DEA is also involved.

Q. BY MR. MOONEY: So there's Board of Medicine licensing and the DEA. Does the State of New York also license prescribers to engage in controlled substance activity?

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MR. ARBITBLIT: Object to form.

THE WITNESS: I'm not sure about the nuances of New York State's rules and regulations regarding licensure and prescribing privileges. If it's similar to other states, then the Board is involved in licensure as well as specifically the DEA is involved in granting permission to prescribe controlled substances.

Q. BY MR. MOONEY: Does the New York Board of Medicine have the power to investigate doctors?

A. Yes.

Q. Can it discipline doctors?

A. Yes.

Q. Can the Board of Medicine take away a doctor's license?

A. Yes.

Q. If a doctor losses their medical license, can they prescribe opioids?

A. No.

Q. They can't practice medicine at all in that state; right?

A. That's right.

Q. Are you familiar with the Federation of State Medical Boards?

A. Yes.

Q. What is the Federation of State Medical Boards?

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A. The Federation of State Medical Boards is the umbrella organization for the individual State Medical Boards.

Q. And is the New York State Medical Board a member of the Federation of State Medical Boards?

A. I assume so.

Q. Are medical boards from all 50 states members of the Federation?

A. I assume so, but I don't know for sure.

Q. Is CardinalHealth, McKesson, AmerisourceBergen or Rochester Drug Co-op a member of the Federation of State Medical Boards?

A. I don't believe so.

Q. As part of its work overseeing State Medical Boards, did the Federation release model guidelines for prescribing opioids?

A. Yes, they did.

Q. And when did the Federation first issue those guidelines?

A. I do reference that in my report.

MR. MOONEY: You can take the time to look, but you might look at page 26.

THE WITNESS: Thank you. I appreciate it.

So the Federation of State Medical Boards published the book -- published a book. In 1998, the

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Federation of State Medical Boards released a policy to reassure doctors that they would not be prosecuted if they prescribed even large amounts of opioids. And then they released a book in 2007 called "Responsible Opioid Prescribing, a Physician's Guide."

Q. BY MR. MOONEY: Okay.

A. Does that answer your question?

Q. Sort of.

Did the DEA endorse the Federation's model guidelines?

A. I don't believe the DEA was involved in endorsing the model guidelines.

Q. Do you know if the DEA testified in support of the Federation's model guidelines?

A. If they did, I'm -- I'm not aware of that.

Q. As part of the Federation's policy, did the model guidelines reassure doctors that they would not be prosecuted if they prescribed large amounts of opioids for the treatment of pain?

A. It is certainly true that through the campaigning of the Pain and Policy Study Group from Wisconsin, Drs. David Joranson and June Dahl, promoted by the American Pain Society and funded indirectly by the opioid manufacturers, that there was a lobbying campaign during which Drs. Joranson and Dahl went to different

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state federation -- different State Medical Boards encouraging them to pass laws and guidelines stating that doctors who prescribed very high amounts of opioids would not be -- would not be punished in any way, as long as they were prescribing those opioids for the treatment of pain.

Q. So --

A. Yes. The answer to your question is "yes."

Q. Right. In romanette II you say: "In 1998, the Federation of State Medical Boards released a policy to reassure doctors that they would not be prosecuted if they prescribed even large amounts of opioids as long as it was for the treatment of pain."

Did I read that correctly?

A. Yes.

Q. And that is an opinion that you hold?

A. That's correct.

Q. Did the Federation urge the State Medical Boards to punish doctors for under-treating pain?

A. Yes, they did.

Q. Has the New York Board of Medicine ever punished doctors for under-treating pain?

A. I'm not aware of specific cases.

Q. Are doctors afraid of being disciplined by their State Medical Board and facing lawsuits if they don't

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prescribe opioids for their patients to address pain?

A. That was true in the late 1990s and early aughts through about 2012 or 2013. I think that's less true now.

Q. Did the New York Board of Medicine implement the Federation's model guidelines?

A. I don't know.

Q. Now, you mentioned a couple moments ago that the Federation also published a book that promoted the use of prescription opioids; is that right?

A. That's right.

Q. And what was the title of that book?

A. Responsible Opioid Prescribing, a Physician's Guide.

Q. And when was that book released?

A. 2007.

Q. Did CardinalHealth, McKesson, AmerisourceBergen or Rochester Drug Co-op provide any funding for that book?

A. Not that I'm aware of.

Q. The Federation didn't just publish the book Responsible Opioid Prescribing, they distributed copies to State Medical Boards; is that right?

A. That's right.

Q. And then the State Medical Boards distributed

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that book to its licensees?

A. I don't know whether they distributed it for free or if it was available for purchase, but it was certainly available to their licensees.

Q. So just so I make sure I understand, the Federation of State Medical Boards of all of the State Medical Boards published a treatment guideline and published a book telling doctors that it's generally accepted medical practice to prescribe the opioids as a first-line treatment for chronic pain.

Is that accurate?

A. So I have read the book Responsible Opioid Prescribing, and I would say that it contains within it many of the misleading promotional messages that I've detailed here in my report, for example, that opioids are an evidence-based treatment for chronic pain. That is a misleading message. That the risk is low or that no dose is too high, et cetera.

There is some good information in that book. It's not all bad information. But there's certainly enough bad information in that book to make it suspect.

Q. Okay. So just focusing in on the question: The Federation of the State Medical Boards published treatment guidelines and published a book telling doctors that it's generally accepted medical practice to

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prescribe opioids for chronic pain; is that right?
A. That's right.
Q. And is it your opinion that these guidelines made the opioid epidemic worse?
A. They contributed, yes.
Q. And is that because the guidelines largely did away with the restrictions that had previously existed on how opioids were prescribed?
A. It's a combination of doing away with the Federation of State Medical Boards' level of scrutiny on how doctors were prescribing opioids, condoning high volume prescribing and high-dose prescribing.
But I think even more importantly, that book was one of many pieces that really changed the culture around opioid prescribing, such that prescribing very high doses and very large volumes, even for minor and chronic pain conditions, became normative in medicine.
Q. Is the New York Medical Board still a member of the Federation of State Medical Boards?
A. I don't know. I assume so, but I don't know.
Q. Do you know if the New York Attorney General has sued the Federation of State Medical Boards for publishing guidelines that contributed to the opioid epidemic?
A. I'm not aware of that.

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Q. Have you publicly condemned your colleagues on State Medical Boards for promoting the model guidelines?
A. Yes.
Q. Where?
A. I've given talks, and in my book, I talk about the role of the Federation of State Medical Boards. I wouldn't say I've publicly condemned certain individual colleagues, but as one brick, you know, in a larger, you know, wall of this problem, the Federation of State Medical Boards has played a role in contributing to the opioid epidemic in the ways that I have just said and also in the ways that I detail in my report.
Q. Are you familiar with the Joint Commission on Accreditation of Healthcare Organizations?
A. Yes, I am.
Q. It's often referred to as the Joint Commission?
A. Yes.
Q. What is the Joint Commission?
A. The Joint Commission is a non-profit organization that was designed to accredit hospitals to ensure that patients are receiving a high level of care. And hospitals and clinics are eager to get Joint Commission accreditation in order to, for example, be eligible for funds from Medicare and Medicaid.
So what the Joint Commission does is establish

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certain quality measures and how to meet those quality measures, and hospitals and clinics who meet those measures can be accredited by the Joint Commission and get a kind of seal of approval, which is very important, has been historically very important for healthcare institutions.
And that seal of approval not only is a public statement to the quality of their care, but again, also makes them eligible for certain types of reimbursement.
Q. And so does meeting those quality measures depend on following the best practices that are determined by the Joint Commission?
A. Yes, meeting those quality measures is dependent on following best practices determined by -- as determined by the Joint Commission and as measured in the way that the Joint Commission says they need to be measured.
Q. And has the Joint Commission introduced standards for the treatment of pain?
A. Yes. In 2001, the Joint Commission made pain a quality measure and implicitly suggested the ways in which hospitals and clinics should implement that quality measure.
Q. And did the Joint Commission's quality measures promote more liberal prescribing of opioids for pain?

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A. Yes. It was a combination not only of making pain a quality measure, but also dispensing to hospitals for a fee educational materials obtained from opioid manufacturers on how that could be done. And those -- those quote/unquote learning materials contained much of the misinformation propagated by defendants that led to this opioid epidemic, things like doctors who don't prescribe opioids for pain are suffering from quote/unquote opioid phobia and implied irrational fear of opioids.
The idea that every pain patient can be assessed using the pain scale from 1 to 10, and that should be assessed using that pain scale, whether or not they appear to have any kind of pain.
The misrepresentation of the risk of opioids, including that patients -- that it's very rare for patients to get addicted to opioids as long as they're being prescribed by a doctor, when, in fact, there is good evidence that predates this epidemic and has been validated in ongoing research that the risk is actually very common among patients treated for pain. That's all in my report.
MR. MOONEY: Move to strike everything after "yes."
Q. My question was: Did the Joint Commission's

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quality measures promote more liberal prescribing of opioids for pain?
A. Yes.
Q. And is it a practical effect of those standards that hospitals had to follow them or risk losing accreditation?
A. Yes, I believe that's true.
Q. Are you familiar with the concept of a vital sign?
A. Yes, I am.
Q. What is a vital sign?
A. A vital sign is an objective measure of a patient's health, including heart rate, breathing rate, blood pressure and temperature. Those four have been the classic and enduring vital signs in medicine for decades.
The Joint Commission advocated pain measure and the 1 to 10 pain scale as another way to -- as a way that doctors should measure pain, and that pain should be like the fifth vital sign. That was the terminology. I don't think the Joint Commission invented that, but in their collaboration with the American Pain Society and key opinion leaders, came up with the idea of pain as the fifth vital sign, and the Commission adopted and disseminated that idea in order to meet their quality measure. So yes.

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Q. And what is the significance of treating pain as a vital sign?
A. The significance of treating pain as a vital sign is that any patient who walks through your office or clinic or emergency room or hospital door for any reason should have their pain assessed along with their blood pressure, heart rate, temperature, et cetera, just as the standard of care.
Unfortunately, there's no evidence to support the use of the visual analog scale, or the 1 to 10 pain scale, in terms of pain outcomes. And in fact, data show that asking patients to rate their pain on a scale from 1 to 10 just leads to more opioid prescribing and doesn't improve pain outcomes.
Q. So did treating pain as a vital sign encourage prescribing more opioids for pain?
A. Yes.
Q. Do patient satisfaction surveys influence doctors to prescribe opioids more liberally?
A. Yes.
Q. How do they do that?
A. As I talk about in my report and also in my book, doctors are kind of natural pleasers and natural helpers, and they are very compassionate people, by and large, and they want to help their patients. And they're

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also eager to have their patients like them. And so that can make that dynamic between doctor and patient and opioid prescribing very complicated.
Because opioids can be effective for pain in the short-term, when doctors prescribe them, patients do endorse significant, immediate relief, and that feels really good for doctors.
And then that's -- the complexity there is added to by the fact that many hospitals ask their patients to rate their doctors on, you know, on how good they are, as well as there are national surveys asking patients to rate the hospital, did your hospital or your clinic do everything in their power to address your pain.
And then those ratings are communicated back to doctors, and if they're not good ratings, then doctors really are called to task on why their patients are not rating them highly, which can contribute to opioid overprescribing.
Q. Have you quantified the impact that patient satisfaction surveys have on doctors' decisions to prescribe opioids?
A. What do you mean by "quantify"?
Q. Well, have you -- can you provide a percentage of a doctor's decision making for which patient satisfaction surveys played a role in prescribing

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opioids?
A. I can't quantify it numerically, but based on my personal experience, my clinical experience, and also my many conversations with doctors, patient satisfaction surveys have played a big role.
Q. Are you aware that the DEA sets a quota on the number of prescription opioids that can be manufactured in a given year?
A. Yes.
Q. Do you agree that the DEA's quota impacts the supply of opioids that are available?
A. I really think it's out of my area to opine on that. There will be other experts who will speak to specific quotas and the legal obligations of manufacturers vis-à-vis quotas. That's not -- not really my area.
Q. My question wasn't about the manufacturer's role in the quota. My question was just do you believe. I understand there may be other experts who are going to opine on this.
My question: Do you agree that the DEA quota has an impact on the supply of prescription opioids that are available in the market?
MR. ARBITBLIT: Object to form.
THE WITNESS: Yes. That makes sense.

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Q. BY MR. MOONEY: Should the DEA's quota be lower?
A. I don't feel that I really know enough about the impact of quotas to be able to offer an opinion on that.
Q. On page 58 of your report, you write that the best evidence available shows that the risk of addiction in patients taking opioids for chronic pain is between 10 percent and 30 percent.
Do you see that?
A. Yes.
Q. Assuming that those percentages are accurate, what is the appropriate number of prescription opioids that a distributor should ship to a pharmacy?
MR. ARBITBLIT: Object to form.
THE WITNESS: That's really outside -- those calculations are outside of my expertise.
Q. BY MR. MOONEY: What percentage of Americans have ever taken a prescription opioid as prescribed by a doctor?
A. So I do talk about that a little bit in my report. Let me refer to that section.
So in 2016, I coauthored an article on the use of opioid agonist therapy in the treatment of opioid use disorder, but as part of the quantitative analysis that we did for this publication, we also assessed the percentage of Medicare Part D enrollees who fill at least

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one opioid prescription in any given year, and we calculated that more than 10 million Part D Medicare enrollees are exposed to a prescription opioid in any given year.
And the Medicare Part D sample is a good sample because Medicare Part D recipients can be found across the country. So it's a very representative sample of the US population.
And although I know that doesn't specifically answer your question of what percentage of Americans have ever taken a prescription opioid, it's a very large number of individuals who have been prescribed an opioid. I can't give you an exact percentage.
And this -- this data point conveys or illustrates that we're talking about tens of millions of Americans.
Q. And in your opinion, is that tens of millions of Americans number too high?
A. Yes.
Q. What should the number be?
MR. ARBITBLIT: Object to form.
THE WITNESS: It's hard for me to say at this juncture what that number should be. I think it should be lower. Exactly how much lower, I'm not sure, but I think it is our responsibility both, you know, in the

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pharmaceutical opioid industry and in the medical profession and representatives in Public Health and across the nation, to try to zero in on what that lower number should be.
Q. BY MR. MOONEY: Do you know if any of the 10 million Part D Medicare enrollees in your report had their claims rejected?
A. I don't know. We did not analyze that.
Q. Do you agree that heroin and fentanyl use in the United States has increased over the past five years?
A. Yes.
Q. Is nonmedical prescription opioid use a significant factor that contributed to the increase in heroin and fentanyl use?
MR. ARBITBLIT: Object to form.
THE WITNESS: Both medical and nonmedical use have contributed to the use in heroin and illicit fentanyl use.
Q. BY MR. MOONEY: What is "nonmedical prescription opioid use"?
A. Nonmedical opioid use means taking an opioid in any way other than indicated by the doctor and by the prescription.
Q. Between medical and nonmedical prescription opioid use, which one of those two has played a larger

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contribution in heroin and fentanyl use?
MR. ARBITBLIT: Object to form.
THE WITNESS: Both have played a very significant role. Legitimate prescription opioid use can lead a patient to engage in nonmedical prescription opioid use, which increases their risk 40-fold then of progressing to heroin use, for the Compton 2016 article.
There's also good evidence via the McCabe 2017 reference in my report that medical use of prescription opioids actually precedes nonmedical use, and that nonmedical use followed by medical use in the McCabe 2019 article exacerbates the development of a substance use disorder.
There's also the scenario in which people in the last three decades, growing numbers have engaged in nonmedical use because of diversion. People who got pills from a drug dealer or from a friend at school or from grandma's medicine cabinet. People who did not interface at all with the medical community, which really speaks to the oversupply of opioids broadly in our society being a major factor in this epidemic.
Q. The Muhuri report, though, said that 70 percent of misusers used illegal drugs before they used opioids; isn't that right?
A. Go to that.

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So as I state in my report, in a study based on the National Survey of Drug Use and Health Data -- this is page 96 of my report -- from 2002 to 2011, the incidence of heroin use among people who reported prior nonmedical use of prescription opioids was 19 times as high as the incidence among persons who reported no previous nonmedical use.

So that's an important data point to show the clear association between nonmedical use of prescription opioids and heroin use. But this is also an incidence study so it doesn't capture the full prevalence of individuals who -- in the population who have an opioid use disorder or use heroin.

So it's an important data point to show the association between nonmedical use and heroin use, but there's also a very strong association between medical use and nonmedical use and then the progression to heroin use.

If you look at page 86 of my report, McCabe 2017. McCabe writes that: "We found that the majority of nonmedical users of prescription opioids involved a history of medical use, and this finding should provide some concern to health professionals who prescribe opioid medications to adolescents, given the serious health consequences associated with nonmedical use of

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prescription opioids."

So there is a very clear stepping-stone effect from medical use to nonmedical use to heroin use. That's not the only pathway. There's also a pathway that begins with nonmedical use, and that's become increasingly more prevalent because of the increased supply, and that then leads to heroin use.

So there's -- those -- those things are closely intertwined.

I would also say that these pieces of evidence from the peer-reviewed literature support my clinical experience, in which I have had countless patients report to me that their opioid addiction began with a prescription from a well-intended healthcare provider for the treatment of pain.

Q. The Muhuri 2013 report found that more than 70 percent of heroin users started with illicit drugs prior to their nonmedical prescription use; is that right?

MR. ARBITBLIT: Object to form.

THE WITNESS: Could I see? I don't have the article right in front of me. I believe you, but it would be nice to look at the actual article.

MR. MOONEY: Mark this as 4, I think.

(Exhibit 4, CBHSQ Date Review, SAMHSA, August

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2013, marked for identification.)

THE WITNESS: Do you have a page that you quoted from?

Q. BY MR. MOONEY: Yes.

First, can you identify what's been marked as Exhibit 4 to your deposition?

A. Yes. This is Muhuri, "Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States."

Q. Now if you would turn to the page that ends at the bottom in 6042, Table 6.

A. Uh-huh.

Q. Just before we talk about that page, I just want to clarify. This Exhibit 4 is the report that you cite in footnote 410 of your report?

A. Yes.

Q. Okay. So Table 6 lays out the percentage distribution of past-year nonmedical pain reliever use among persons age 12 to 49 at risk for initiation of nonmedical pain reliever use by prior drug use status.

Is that right?

A. Uh-huh, uh-huh.

Q. And under the "no heroin use prior to NMPR use, is "NMPR" --

A. Uh-huh.

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Q. -- nonmedical pain reliever use?

A. Uh-huh.

Q. It says: "Other illicit drug use" -- "drugs used prior to NMPR use."

Do you see that?

A. Uh-huh.

Q. If you go to the right, under the column 2002 to 2011, it says 71.8 percent; is that right?

A. Uh-huh.

Q. And so does this table say that 71.8 of persons who did not use heroin before using nonmedical pain relievers -- or excuse me -- using pain relievers for nonmedical use, were using other illicit drugs before eliciting nonmedical pain reliever use?

A. Yes, it does say that.

Q. And then footnote 2, which follows other illicit drugs, reads: "Other illicit drugs include marijuana, hashish, cocaine, including crack, hallucinogens and inhalants."

Did I read that right?

A. Yes.

Q. Of all the people -- you can set that aside.

Of all the people who get an opioid prescription from their doctor, how many go on to use heroin or fentanyl?

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A. Well, that's a different question.
Q. It is.
A. That's based -- yeah. So I think you've asked that before. The most reliable version of that -- let me try to answer, again, we're better.
So the most reliable data show that approximately 10 to 30 percent of patients treated with an opioid for pain have some kind of opioid use disorder, and it's the natural history of the disease of addiction that patients will over time need more and more of that opioid to get the same effect and that they will look for cheaper and more readily available sources.
So when -- once people are addicted through a prescription opioid, it is not uncommon for them to then progress to heroin, and we do know that our heroin supply has been adulterated by illicit fentanyl.
And so, you know, I don't have data exactly on how many of those patients addicted through a prescription progressed to heroin, but the odds ratios from Compton 2016 show that they are 40 times more likely to progress to heroin use having been exposed to a prescription opioid.
And again, the McCabe and my own experience suggests that a very large proportion of individuals who have become addicted to heroin in the last 20 to 30 years

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started out with a prevention opioid.
There's also an article that I reference here based on a survey study showing that three-quarters of heroin users say that their first exposure to opioids was a prescription opioid. And that's page 96, Cicero, JAMA Psychiatry 2014.
And I'll just read from that. "In the 1960s, 80 percent of opioid users reported that their first exposure to opioids was in the form of heroin. By the 2000s, however, 75 percent of opioid users reported that their first exposure to opioids was in the form of prescription painkillers," really demonstrating a massive paradigm shift in terms of the heroin users in this country today compared to the 1960s.
MR. MOONEY: Move to strike all of that.
Q. Dr. Lembke, my question was: How many people who get opioid prescriptions from their doctor end up going on to use heroin or fentanyl?
MR. ARBITBLIT: Object to form.
THE WITNESS: I couldn't give you an absolute number. I've tried to suggest an answer through percentages.
Q. BY MR. MOONEY: So sitting here today, you cannot provide a number of how many people who are prescribed opioids by their doctor end up using heroin or

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fentanyl; is that correct?
MR. ARBITBLIT: Object to form.
THE WITNESS: Well, I did prescribe a number that I think is very evidence based and reliable on what percentage of patients prescribed an opioid by their doctor for a legitimate pain condition will go on to develop an opioid addiction, somewhere between 10 and 30 percent, which is very common.
And then if we extrapolate from that that we've got tens of millions of Americans, you know, who are exposed to opioids, you know, you could come up with a number for that.
Q. BY MR. MOONEY: Can you come up with a number for that sitting here today?
A. I'd rather not give a specific number. I think the evidence is in my report and based on percentages.
Q. So the answer is "no," today, sitting here, you can't give a number?
A. Yes, that's right.
Q. On page 85 of your report in paragraph D, you write: "It is important to recognize that although many of the communities hit hardest by the opioid epidemic were already struggling with serious social and economic problems, the sudden availability of easy access to opioids, initially in prescription pill form, contributed

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to the economic and social devastation of many towns across America."
Did I read that correctly?
A. Yes.
Q. You're not an economist, are you?
A. No.
Q. Are you a sociologist?
A. Armchair sociologist?
Q. Trained -- trained sociologist?
A. I don't have any degrees in sociology, per se.
Q. Have you done any independent analysis of economic and social devastation across many towns in America?
A. No.
Q. Have you done any independent analysis of the causes of any economic and social devastation across many towns in America?
A. No.
Q. Do you have any other opinions about distributors that are not listed in your report, that you intend to offer in this litigation?
A. My opinions in the report as well as in my testimony today are the opinions I intend to offer in this litigation.
Q. When we started this deposition, I handed you

what was marked as Exhibit 1.
Do you remember that?
A. Yes.
Q. And you said Exhibit 1 was a -- or excuse me, Exhibit 2. I meant to say Exhibit 2. I handed you Exhibit 2.
A. Yes.
Q. And that was your report from your -- from this case; is that right?
A. Yes, that's correct.
Q. And you have not referred to that report in the course of answering your -- answering my questions during today's deposition, that physical copy that is marked as Exhibit 2; right?
A. That's correct.
Q. You came in with a binder today that includes Post-It notes and notations?
A. Yes.
MR. MOONEY: I would like to mark that document as Exhibit 5 to this deposition.
MR. ARBITBLIT: No objection.
(Exhibit 5, Dr. Lembke binder, notes and notations, marked for identification.)
MR. MOONEY: We can take a break.
MR. ARBITBLIT: Are you releasing the witness or

not? You're just going to go think about it?
MR. MOONEY: We've got to go see what that document is.
MR. ARBITBLIT: Fair enough.
THE VIDEOGRAPHER: Going off the record, the time is 11:27 a.m.
(Lunch recess.)
THE VIDEOGRAPHER: Back on the record. The time is 12:16 p.m.
MR. MOONEY: Dr. Lembke, I have no further questions. Thank you for your time.
THE WITNESS: You're very welcome.
EXAMINATION
Q. BY MR. CARTER: Good afternoon, Dr. Lembke.
A. Good afternoon.
Q. My name is Ed Carter. We have not met before, but I represent Walmart, and I have some questions to you today, okay?
A. Yes.
Q. Can you identify any false or misleading claim about opioids made by one of the retail pharmacy defendants in this case?
A. No.
Q. Are you aware of any marketing of opioids conducted by any of the retail chain pharmacy defendants?

A. No.
Q. Are you aware of any pharmacy presenter at the 2001 CME that you attended?
A. Not that I recall.
Q. And am I correct in your report for this case, you have not identified any marketing statements by retail pharmacy defendants; correct?
A. That's correct.
Q. In preparing your report for this case, did you consider any documents produced from the files of a pharmacy defendant?
A. No.
Q. Have you reviewed the testimony of any employees or witnesses from a pharmacy defendant in connection with your work in this case?
A. No.
Q. Earlier today you had some comments regarding the responsibility of pharmacists. I want to follow up on that, okay?
You mentioned that pharmacies also have a responsibility in the opioid supply chain to make sure that a patient customers are not being harmed by the opioids that are dispensed.
Do you recall saying that?
A. Yes, I do.

Q. Okay. Is that opinion reflected anywhere in your report for this case?
A. It's reflected broadly in my opinion that the oversupply of opioids to Americans has been a major contributor to this epidemic of addiction and overdose death.
Q. Does that specific claim or opinion, is that noted anywhere in your report, the one that I just read to you?
A. I don't specify a pharmacy in my report.
Q. And in your report, you do not mention any pharmacy by name; correct?
A. That is correct.
Q. With respect to the statement you made this morning regarding pharmacy responsibility to make sure that patients are not being harmed by the opioids that are dispensed, do you have any opinion in this case that any of the pharmacy defendants did not comply with that responsibility you articulated?
A. I am aware based on reports in the lay press and in other non-confidential documents and readings that I have done that there are rogue pharmacies out there dispensing very large quantities of opioids, far more opioids than can be justified by the need for analgesia in that community, and I don't know if any of those are

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either -- are Walgreens or Walmart.
Q. Okay. Do you know who the pharmacy defendants are in the case brought by Nassau County?
A. I believe Walgreens and Walmart are the pharmacy defendants in the case brought by Nassau County. CVS may also be included, but I'm not sure.
Q. All right. Any other defendants that you're aware of as defendants in the Nassau County case?
A. No.
Q. Do you know who the pharmacy defendants are in the Suffolk County case?
A. I believe it's the same pharmacies.
Q. Okay. Any evidence that Walgreens, Walmart or CVS in Nassau County failed to comply with the responsibility to ensure that their patients, customers, were not being harmed by the opioids that they dispensed?
A. I don't have knowledge of the specific pharmacies in those counties.
Q. Fair to say you have not conducted any systematic analysis or review of pharmacy dispensing data in Nassau County?
A. Let me look at my report. I have reviewed data on page 17 as pertains to the morphine milligram equivalents dispensed in the state of New York, including Nassau and Suffolk Counties, as well as the duration of

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prescriptions, namely, that in the state of New York, opioid prescribing increased from 101 morphine milligram equivalents in 1997 to 442 morphine milligram equivalents by 2006, and again increased to 492 morphine milligram equivalents per person in 2016, and this correlates with the four-fold increase in opioid-related deaths in the state of New York in that time period.
Also, the length of opioid prescriptions increased during that time, going from 15 days in 2006 to 19 days of opioids in 2017.
I also have CDC data looking at the opioid prescribing rates specifically in Nassau County, which increased from 47 opioid prescriptions per 100 persons to 51 opioid prescriptions per 100 persons from 2006 to 2011.
And in Suffolk County, I reviewed data showing that opioid prescriptions increased from 61 opioids per 100 persons to 70 prescriptions per 100 persons in 2011.
Those are data that I reviewed specifically regarding opioid prescribing in Nassau and Suffolk County and New York, in the state of New York.
Q. Do you know, are any of those data sources pharmacy dispensing data sources?
A. I believe that the CDC data, the number of opioid prescriptions per 100 persons is based on

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pharmacy dispensing data.
Q. Have you heard of ISOP?
A. What does "ISOP" stand for?
Q. I'm asking you. Have you heard of that acronym?
A. Oh. I don't know the acronym. I might know if you tell me what it stands for. It might ring a bell.
Q. Have you reviewed the State of New York's PMP drug data?
A. Is that the prescription drug monitoring database in the State of New York?
Q. Yes.
A. No, I have not.
Q. And with respect to any specific pharmacy in Nassau or Suffolk, have you analyzed their dispensing history to determine whether that pharmacy has adequately attended to the safety of their customers?
A. No, I have not.
Q. You also discussed earlier today the following statement. You said that pharmacists have a responsibility to patients to ensure that the prescription is appropriate, that it is a true prescription, and that it is not a prescription that will harm the patient.
Do you recall giving that testimony?
A. Yes, I do.

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Q. Okay. Is that -- are any of those statements contained expressly in your report for this case?
A. Not expressly in my report, no.
Q. Do you know whether Walmart -- strike that.
Do you have any opinion whether Walmart fulfilled its responsibility, as you described it, to ensure that its patients had appropriate prescriptions, true prescriptions, and prescriptions that would not harm the patients?
A. Yes, I do.
Q. Okay. And what is your opinion?
A. I considered Walmart to be a critical actor in the opioid supply chain, and the behavior of all the defendants in the opioid supply chain contributed to the oversupply that was the primary factor in driving the current opioid epidemic. So Walmart does bear some responsibility in the epidemic.
MR. CARTER: All right. I'll respectfully move to strike and reask my question.
Q. Do you know whether Walmart fulfilled its responsibility, as you described it, to ensure that patients had appropriate prescriptions in Nassau County or Suffolk County?
MR. ARBITBLIT: Object to form.
THE WITNESS: I believe that Walmart did not

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fulfill its responsibility because Walmart is part of the opioid supply chain.
Q. BY MR. CARTER: So what patient, either a name or a case number, did Walmart fail to fulfill its responsibility to ensure that it was an appropriate prescription and a true prescription in Nassau and Suffolk County?
A. I don't have those details.
Q. And where in your report do you articulate the opinion that Walmart failed to fulfill its responsibility in those regards?
A. I don't specifically name Walmart in my report.
Q. Same question with respect to Walgreens and CVS.
A. Same answer.
Q. Okay. You also said that pharmacists have a responsibility to check drug interactions and indications.
Do you recall that?
A. Yes, I do.
Q. Is that opinion reflected anywhere in your report?
A. Not specifically.
Q. And do you have any evidence that Walmart, Walgreens or CVS failed to check drug interactions or indications for any patient in Nassau or Suffolk County?

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A. I -- pursuant to my prior response, I think that applies here. To the extent that Walmart, Walgreens or CVS are key in the opioid supply chain, they bear some responsibility for the opioid epidemic. But I don't have specific information on specific pharmacists in the Suffolk or Nassau counties.
Q. Did I -- what in my question led you to conclude I was asking about responsibility?
MR. ARBITBLIT: Object to form.
THE WITNESS: Because your question was a follow-up to my response earlier in the deposition where I said that pharmacists bear some responsibility and that there are precautions that pharmacists can make -- can take. Sorry.
Q. BY MR. CARTER: Do you have any understanding of the role of community pharmacists as individual license holders versus corporate policies for retail pharmacy or pharmacy chains? Is that an area of your expertise?
A. I would say I'm more familiar with the responsibilities of individual pharmacists, having interacted with them over my 20-plus-year career.
Q. Now, you also said that pharmacists play an important role in educating patients about the risks and benefits of medications.
Do you recall that?

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A. Yes, I do.
Q. Do you know how Walmart pharmacists performed their role of educating patients about the risks and benefits of prescription opioids in Nassau County or Suffolk County?
A. No.
Q. Have you studied that for any pharmacy defendant in the Nassau County or Suffolk County case?
A. No, I haven't.
Q. Do you have any knowledge of what information pharmacists in Nassau County provide to patients at the time of dispensing prescription opioids during the relevant time periods for the Nassau County case?
A. No.
Q. Same question for Suffolk County pharmacists.
A. Same answer.
Q. You also testified that pharmacists have a health-safety relationship with their patients.
Do you recall that?
A. Yes.
Q. Okay. Do you have an opinion -- well, strike that.
Does that statement appear anywhere in your expert report for this case?
A. I don't believe so, no.

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Q. Do you have an opinion whether Walmart or any pharmacy defendant violated in some way the health-safety relationship with patients?
A. Again, to the extent that pharmacists are an important link in the opioid supply chain, and given the data of overdose deaths and addiction in Nassau -- Nassau and Suffolk counties, I think it's fair to say that every member of that opioid supply chain failed to some extent in their responsibilities vis-à-vis their patients and the public in that community.
Q. And does that opinion appear anywhere in your report?
A. Not specifically, but I do talk at length in my report about supply of opioids and access to opioids as a major risk factor for addiction to opioids. I have an entire section in my report called "The Tsunami Effect," which specifically refers to the rising tide of the number of pills in the community, increasing access both through legitimate and illicit means, putting the population at risk.
Q. Sitting here today, are you able to assign a numeric value, either a percentage or a raw number, of instances in which you contend a pharmacy defendant in Nassau County failed to fulfill the health-safety relationship with patient-customers?

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A. I can't put a number on it, but I believe that the pharmacies bear some -- some blame.
Q. Same question for Suffolk County.
A. Yeah, same answer.
Q. Do the doctors who wrote prescriptions in Nassau County bear responsibility and some measure of blame?
A. Yes, they do.
Q. Same question for Suffolk.
A. Same answer.
Q. Okay. You also noted earlier that pharmacists should be aware of the CDC guidelines that opioid should not be used as first-line treatment.
Do you recall that?
A. Yes, I do.
Q. Do you know whether any Walmart pharmacist in Nassau County was unaware of those CDC guidelines?
A. No, I don't have information at that level of specificity.
Q. Any opinion that any pharmacist for any of the pharmacy defendants in the Nassau or Suffolk County case was unaware of the CDC guidelines?
A. I have no specific knowledge about that.
Q. You also mentioned that pharmacists should have good old common sense.
Do you recall that?

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A. Yes, I do.
Q. Does that appear anywhere in your report?
A. No.
Q. Okay. Any evidence that a Walmart pharmacist in Nassau County failed to exercise good old common sense?
A. As I answered before, the evidence as to the absence of exercising good old-fashioned common sense is the scourge of addiction and death due to prescription opioids in those counties and in the state of New York more broadly.
Q. Do you understand the pharmacy defendants are not involved in the State of New York's case? Or do you know that now that I said it?
A. So the defendants have changed, and so I -- I haven't tracked exactly who's in what litigation. I'm more broadly aware of the defendants as part of the opioid supply chain.
Q. What aspect of common sense did a Walmart pharmacist in Nassau County fail to exercise?
A. To the extent that there were pill mills in Nassau and Suffolk County and a pharmacist filled prescriptions for a pill mill doctor without trying to make some effort to scrutinize or change the course of that prescribing pattern, that pharmacist has responsibility.

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To the extent that the pharmacists in Suffolk and Nassau County were filling prescriptions for very high doses of opioids or for very long duration or in combination with benzodiazepines or in combination with other sedative hypnotic-type drugs, increasing that individual's risk of accidental overdose death, that pharmacist had some responsibility.
Q. Do either of those scenarios appear anywhere in your report?
A. Those scenarios are implied in my report in my discussion of the problem of oversupply, the ways in which healthcare providers were duped based on a misrepresentation of the science regarding the safety and efficacy of opioids.
The evidence that I've cited in my report and in this deposition regarding the large increase of opioids in Nassau and Suffolk Counties, data showing that an increase in opioid prescribing in a given geographic region correlate with increased rates of addiction and overdose death in those counties, that's all implied.
Also, I would just say that in my greater body of work, including in my book and other talks I've given and other peer-reviewed literature that I've written, I have talked at length about not the role of pharmacists specifically, but the role in general of healthcare

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providers vis-à-vis the epidemic.
Q. Any other evidence that those hypotheticals actually occurred in Nassau County at a Walmart pharmacy?
A. I don't have specifics on that, no.
Q. Same question for any of the pharmacy defendants.
A. Same answer.
Q. And then same question for Suffolk County for all pharmacy defendants.
A. Same answer.
Q. You mentioned -- and you've testified about it before -- the idea of well-intentioned, well-meaning physicians exercising their best medical judgement and being duped.
Do you recall that?
A. Yes, I do.
Q. Is it fair to say that if a well-intentioned, well-meaning physician who is setting out endeavoring to exercise their best medical judgment under the circumstances is duped, that there's no reason to think a pharmacist would also -- that a pharmacist would not also be duped?
A. Can you rephrase the question?
Q. Sure.
If doctors were duped, do you agree that

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pharmacists were duped?
A. So I'm not familiar with the types of specific continuing medical education that pharmacists receive. It's not something that I've looked into or studied. But I think it's plausible that if -- if doctors were duped, pharmacists were also subject to the same kinds of misinformation, but I really haven't studied that.
Q. Appreciating that you haven't studied the continuing education requirements of pharmacists, based on your experience as a licensed physician, do you have any reason to believe that the substantive medical training that a pharmacist receives is more robust than a M.D.?
A. I really wouldn't want to offer an opinion on whether or not it's more or less robust. To me, robust is a vague term. I'm not really sure what you mean. And also, as I said, I'm not familiar with the continuing medical education or licensure training that pharmacists receive.
Q. Do you think pharmacists receive more substantive medical training than licensed doctors?
A. I feel like I answered that.
Q. So you don't know one way or the other?
A. I don't know.
Q. So it's possible that pharmacists actually have

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more in depth medical training than licensed physicians?
MR. ARBITBLIT: Object to form.
THE WITNESS: They would have a different type of training, but it could be equally in depth.
Q. BY MR. CARTER: Okay. You also said earlier that if someone -- if a pharmacist observed someone intoxicated, that should play into the pharmacist's decision making in determining whether to dispense.
Do you recall that?
A. Yes, I do.
Q. Any evidence that a pharmacy -- pharmacist at a pharmacy defendant in Nassau County dispensed medication to an intoxicated patient?
A. I have no specific knowledge of Nassau County in that regard.
Q. Same question for Suffolk.
A. Same answer.
Q. Do you know how many pharmacies are in Nassau County?
A. No.
Q. Do you know how many are in Suffolk County?
A. No.
Q. Do you know how many are in the state of New York?
A. No.

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Q. Do you know what percentage of the pharmacy market in Nassau County the pharmacy defendants represent?
A. No, I do not.
Q. Same question for Suffolk.
A. Same answer.
Q. Have you conducted any analysis to determine which pharmacies in Nassau County were filling too many opioid prescriptions?
A. No, I haven't.
Q. Have you conducted any analysis to determine which pharmacies in Suffolk County were filling too many prescriptions?
A. No, I have not.
Q. Statewide, have you conducted any analysis to determine which pharmacies in New York state were filling too many prescriptions?
A. No.
Q. In exhibit -- I believe it's C to your report, you provide a testimony rate schedule, and I just wanted to ask you about your $800 per hour for trial testimony.
A. Uh-huh.
Q. When you travel, do you bill for your time as well or only expenses?
A. You mean do I bill for travel time?

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Q. So when you travel to trial in this case, if you testify, will you bill for your travel time?
A. I will bill to be reimbursed for my travel, and I will bill for my travel time as well.
Q. If you hypothetically have to arrive in Long Island on a Monday and you don't take the stand until Wednesday, would you charge at your hourly rate for your time waiting to testify on Monday and Tuesday?
MR. ARBITBLIT: Object to form.
THE WITNESS: No, I would not unless I spent some portion of Monday or Tuesday working to prepare for the trial.
Q. BY MR. CARTER: Have you submitted any invoices for the New York cases that have not been paid?
A. Yes.
Q. Okay. Do you know the amount of unpaid pending invoices?
A. No, I do not.
Q. Okay. You were asked a question earlier regarding the percentage of your income from your work consulting and testifying in litigation versus your work at Stanford. You indicated you could not provide an estimate. I want to just follow up.
Do you know whether your consulting income was more or less than 50 percent of your income last year?

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A. I believe it was less, but it's not something that I've actually sat down and added up and calculated.
Q. Okay. Switching gears, I want to ask you about addiction.
Do you agree that, at least in theory, all addictions can be overcome?
MR. ARBITBLIT: Object to form.
THE WITNESS: So addiction is a disease, and just like cancer, some cases of addiction are terminal and some are curable or can go into remission for a period of time.
I would say the same is true for addiction. It's a chronic, relapsing and remitting disease. Some people with one course of treatment can be in remission from their addiction for the rest of their lives, and that can mean decades.
Other people, even with aggressive treatment, may not be able to achieve remission and may, in fact, die of their disease.
Q. BY MR. CARTER: In your role as someone who treats people with substance use disorders, have you ever approached a treatment -- a treatment of a particular patient and advised them that they would not be able to overcome their addiction and the treatment would not yield productive results?

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MR. ARBITBLIT: Object to form.
THE WITNESS: There's always room for hope. You know, I would never deprive a patient of hope. Even if I worked in a hospice setting where death was eminent, there is still room for hope.
What I certainly would not do is recommend a treatment that caused more harm than good, and I would be very active in finding the best possible treatment for my patient.
Q. BY MR. CARTER: And it's fair to say that absent some kind of involuntary commitment situation, putting that aside, it's fair to say that in general, for a patient to quit use of a substance, break a cycle of addiction and achieve abstinence, that requires an intentional act on their part to try and abstain?
A. So that -- that question -- the answer to that question is nuanced because it's very clear that in the disease of addiction, some patients lose their capacity for voluntary choice, meaning that even when they deeply desire to abstain from the substance, they're not able to abstain. Hence a residential treatment setting for chemical dependency or addiction is an appropriate setting for the individual who's lost their capacity for voluntary choice.
Q. And my question was meant to be a simpler one.

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Let me try it this way.
You are not able to quit on behalf of your patients.
MR. ARBITBLIT: Object to form.
Q. BY MR. CARTER: True?
MR. ARBITBLIT: Object to form.
THE WITNESS: That is true.
Q. BY MR. CARTER: You've never been able to get a patient to quit against their will, absent some kind of involuntary commitment setting?
A. Well, again, it's important to acknowledge that the disease of addiction is actually a disease of the will on some level. And so when I treat addiction, I'm trying to help a patient regain their ability for willful choice.
Q. And to make a quit attempt, in the general course, a patient needs sufficient internal motivation and external support. Fair?
MR. ARBITBLIT: Object to form.
Q. BY MR. CARTER: To make an attempt.
A. Uh-huh. So I have seen cases of addiction where the internal motivation is nonexistent, and yet external encouragement can make it possible for that person to abstain for a sufficient period of time such that they can get their frontal lobe reengaged with their limbic

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system to be able to make a voluntary choice about their consumption of that addictive substance.
Q. BY MR. CARTER: What is DSM-5?
A. The Diagnostic and Statistic Manual of Disorders, Fifth Edition.
Q. And how do you use that as a psychiatrist?
A. I use it with a grain of salt. It is an imperfect way to categorize mental illness. It's also to some extent a dictionary for communication among healthcare providers.
I do use those criteria to make diagnoses, but I also take other considerations into account in forming my treatment plan.
Q. So you have used the criteria, the diagnostic criteria and framework for an opioid use disorder as set forth in DSM-5; correct?
A. Yes, I have used those criteria.
Q. And the fifth edition was published in 2013; correct?
A. I believe so.
Q. It followed DSM-4-TR; correct?
A. Yes.
Q. And I believe you testified to this earlier, but fair to say that if an opioid use disorder under the framework articulated in DSM-5 includes a spectrum of use

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disorders?
A. That's correct.
Q. It ranges from mild, moderate to severe, for those that have a use disorder?
A. That is correct.
Q. And is it fair to say that as a clinician attempting a diagnosis of an opioid use disorder, you want to see and you personally would expect a 360-degree view of all the circumstances involved in making that assessment of a patient?
MR. ARBITBLIT: Object to form.
THE WITNESS: Can you define what you mean by 360-degree view?
Q. BY MR. CARTER: So if you're approaching in a clinical setting a potential diagnosis and you're evaluating someone for an opioid use disorder, you want to see and evaluate the full context that's available to you in that setting?
A. Yes, I would do that.
Q. And you would consider all of the medical history and data and patient evaluation available to you as the clinician; correct?
A. Yes, unless there was a piece of evidence that was so glaring and obvious that I would not necessarily be required to imminently rely on all the other pieces of

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information, although I would still want to gather those over time. Which is to say I -- I may make a diagnosis even absent a 360-degree view if there were -- was a data point that made it very obvious.
Q. Have you ever diagnosed a patient in a clinical setting with an opioid use disorder based on aggregate statistics in lieu of that patient's individual clinical presentation?
A. To some extent, yes.
Q. So you have not conducted an analysis of a patient, not figured out their substance use history, their pattern, and run it through the criteria of DSM-5. Instead of that, you've relied on aggregate statistics to make a diagnosis.
Is that --
MR. ARBITBLIT: Object to form.
THE WITNESS: No, that's -- that's not correct. I don't rely on aggregate statistics to make that diagnosis. But I do allow the reading of the science to inform my interpretation of the specific clinical data that I gather on a patient.
Q. BY MR. CARTER: You apply your clinical judgment and medical training which includes all of the constellation of factors that you've considered in the course of your work and education; correct?

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A. I apply my clinical judgment with a healthy dose of skepticism around the fact that much of the education that I have received has been adulterated by corporate interests. And so I really have to do an extra due diligence and dig deeper to know what the truth is.
Q. Now, you testified earlier that data that shows a range of 10 to 30 percent as a prevalence of somewhere on the spectrum of an opioid use disorder for people using opioids for chronic pain; correct?
A. Yes.
Q. I want to take the other end of that population. So I want to use your 30 percent as the best data on the high end and say, okay, so the other 70 percent, the 70 percent that aren't somewhere on the opioid use disorder spectrum, is it fair to say that millions of Americans have used opioids and not developed an opioid use disorder?
A. That's fair to say, except that you also want to take into account the fact that they may be at ongoing risk for developing an opioid use disorder, even if they haven't developed it yet.
Furthermore, those individuals not meeting the criteria for an opioid use disorder may nonetheless suffer severe adverse medical consequences as a result of their prolonged opioid therapy.

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So it's essential that we, as healthcare providers, do a careful risk-benefit assessment informed by the unique patient history, as well as the evidence showing that there is no robust or reliable data for long-term efficacy of opioids and then enormous risk in continuing opioids long-term.
Q. But to the -- to the basic statistical point, you agree that as a matter of arithmetic, there are millions of Americans who have taken opioids for chronic pain and not developed, to this point in time, some version of an opioid use disorder?
MR. ARBITBLIT: Object to form.
THE WITNESS: Well, I agree as a matter of statistics that there are millions of Americans who have not necessarily developed an opioid use disorder, but those individuals are still at high risk, and that's the point that I'm trying to make.
Q. BY MR. CARTER: Okay. Do you agree that there are millions of Americans who have used opioids for chronic pain and not gone on to take any kind of illegal drug?
A. Yes, I agree.
Q. Do you agree that there are millions of Americans who have taken opioids for chronic pain and not committed any crime related to obtaining substances?

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A. Yes.
MR. CARTER: Okay. I'm going to mark as Exhibit 6, a page from DSM-5. This is the one I already premarked.
(Exhibit 6, Opioid Use Disorder, DSM-5, page 543, marked for identification.)
Q. BY MR. CARTER: Now, after DSM provides the criteria for diagnosis, it also includes statistics and commentary about the framework for the various diagnoses contained within it; correct?
A. Yes.
Q. And I want to ask you about the highlighted language on page 543 under the heading "Prevalence." The first sentence: "The 12-month prevalence of opioid use disorder is approximately 0.37 percent among adults age 18 and older in the community population."
Did I read that correctly?
A. Yes.
Q. I want to read the next sentence.
MR. ARBITBLIT: Before you do, I just want to put an objection to the incomplete document that's being provided.
MR. CARTER: That's fine.
MR. ARBITBLIT: And the lack of the references that DSM-5 undoubtedly cites elsewhere in the document

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that you have not provided.
Q. BY MR. CARTER: Okay. You have a copy of DSM-5, Doctor; correct?
A. I do.
Q. The second sentence --
A. But not right here with me.
Q. Yes.
"This may be an underestimate because of the large number of incarcerated individuals with opioid use disorders."
Did I read that correctly?
A. Uh-huh.
Q. All right. Then I want to read from the last paragraph in that section that makes a comparison to Europe.
"The 12-month prevalence of problem opioid use in European countries in the community population ages 15 to 64 years is between 0.1 percent and 0.8 percent."
Did I read that correctly?
A. Uh-huh.
Q. The next sentence reads: "The average prevalence of problem opioid use in the European Union and Norway is between 0.36 percent and 0.44 percent."
Did I read that correctly?
A. Uh-huh.

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Q. Is that a "yes"?
A. Yes, you read that correct.
Q. Now, when you look at the statistic DSM-5 quotes, the first one we read, the 0.37 percent that's an American statistic, that falls within the 0.36 and 0.44 numbers that are the average prevalence for the European Union and Norway; correct?
A. Yes.
Q. Okay. Have you ever written to the American Psychiatric Association suggesting revisions or corrections to DSM-5?
A. No, but it's a good idea.
Q. Okay. So do you dispute the numbers -- well, let's take each of these in -- in part.
Do you dispute the 12-month prevalence of opioid use disorder of 0.37 percent for Americans age 18 and older?
A. Can I read this document before I answer?
Q. Sure.
A. Okay.
(Interruption in proceedings.)
THE WITNESS: Okay. Yes. Thank you.
Q. BY MR. CARTER: So my question is: Do you dispute the number in the first paragraph under prevalence reported for 12-month prevalence in America?

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A. So I would really like to see what they base these numbers on. That would be a good place to start. And if I could review those, then I would have more to say.
But in general, I -- I believe that reliable sources quote about 2 to 4 million Americans have an opioid use disorder in this country, with some reports as high as 15 million Americans with opioid use disorder when you included marginalized populations like incarcerated individuals, which was not done for this calculation.
Q. Okay. Thank you.
A. Yeah.
Q. You can put that aside.
A. Okay.
Q. Have you analyzed the medical examiner overdose death data from Nassau County? It's not in your list of sources, but...
A. Yes. It's not in my list of sources, but I did review the Keyes reports, which does analyze some overdose death data, and I did include on page -- sorry, let me find the page.
Q. I'll withdraw the question and ask you a similar one.
A. Okay.

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Q. Do you have an opinion in this case as to the number or the identities of any particular case numbers in Nassau County where a decedent was diagnosed with an opioid use disorder?
A. No.
Q. Any such opinion for Suffolk County?
A. No.
Q. Are you able to look at the medical examiner's chart of reported deaths and individually diagnose the subjects referenced there with an opioid use disorder during the course of their life?
A. Are you asking me if I have done that or if I would be able to do that?
Q. So first question: Have you?
A. I have not.
Q. And that applies to Suffolk County as well?
A. That's correct.
Q. Okay. Looking at an autopsy report that lists toxicology at time of death, does that information by itself provide an individual's substance use history?
A. It might be indicative, but probably in and of itself not sufficient.
Q. Is there a posthumous test for addiction or an opioid use disorder?
A. So the diagnosis of addiction, there's no

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biological test for that. There's not a brain scan or blood test. It's the accumulation of multiple sources of evidence based on behaviors, but not just patient self-report, other objective data of their behavior, including potentially a coroner's report indicating what substances were in their system at the time of death.
Q. Are you aware of any specific case in Nassau County where an individual only ever used opioids as directed under the care of a physician in the amount directed and yet died of an overdose from that prescribed opioid?
A. I'm not aware of cases like that in Suffolk or Nassau counties, but I am aware of cases like that in my own medical experience.
Q. Okay. I want to ask you a couple questions about materials you considered.
Have you interviewed any doctor practicing in Nassau County for purposes of offering your opinions in this case?
A. I haven't interviewed -- I haven't set out to interview doctors specifically for the purposes of this litigation, but I have traveled to New York and talked to doctors who have experiences, and based on those conversations, I have gathered knowledge about the situation in New York.

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Q. To your knowledge, do any of the doctors that you encountered in the setting you described practice in Nassau County?
A. I don't know.
Q. Do you know whether any of those doctors practice in Suffolk County?
A. I don't know.
Q. Okay. Have you interviewed any employee of Nassau County or Suffolk County for purposes of forming your opinions in this case?
A. No.
Q. Have you interviewed any resident of Nassau County or Suffolk County for purposes of forming your opinions in this case?
A. No.
Q. Have you interviewed any law enforcement personnel in Nassau County or Suffolk County for purposes of forming your opinions in this case?
A. No.
Q. Have you interviewed any community pharmacists in Nassau County or Suffolk County for purposes of forming your opinions in this case?
A. No.
Q. And taking out the qualifier of purposes of forming your opinion, have you ever interviewed a

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community pharmacist in Nassau County or Suffolk County, to your knowledge?
A. No.
Q. Do you know how the opioid crisis in Nassau County in 2020 compares to the situation in 2015?
A. So the opioid epidemic, including in the state of New York, has heavily impacted the foster care system.
Q. And just to be clear, I want to just remind you I'm only focused on Nassau County, and then I'll have a separate question for Suffolk.
A. Okay.
Q. If that can guide your answer, I'd appreciate it.
A. Okay. Well, I don't have data specific to Nassau or Suffolk County in my report and in my answer, but I do have for the State of New York.
Q. Okay. Since I'm not -- my client's not in the New York case, I'll let others ask you about broader New York data.
A. Okay.
Q. Switching gears, is it fair to say that the majority of prescriptions for opioids in Nassau and Suffolk County were made in good faith for a legitimate medical purpose?
MR. ARBITBLIT: Object to form.

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THE WITNESS: I would not want to opine on whether it was the majority or the minority of prescription opioids that have -- I -- I -- it is both the prescriptions made in good faith and prescriptions made not in good faith that have contributed to the opioid epidemic across this, country including in Suffolk and Nassau County, which I do not believe are rare or unusual or differ in any substantial way from the rest of the United States.

Q. BY MR. CARTER: Without asking you to give a qualitative comparison in terms of majority or minority, do you agree that there are -- there were hundreds of thousands of prescriptions for opioids in Nassau and Suffolk counties that were made in good faith for a legitimate medical purpose?

MR. ARBITBLIT: Object to form.

THE WITNESS: I would agree that many of the prescriptions for opioids that actually led to harm, both in individuals to whom they were prescribed as well as other individuals who became exposed to opioids through the oversupply, were made in good faith by the prescribing physician.

Q. BY MR. CARTER: And there were also prescriptions that did not lead to harm that were made in good faith by the prescribing physician?

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A. I think it's a minority of those prescriptions that did not lead, that has not lead, that is not continuing to lead to some degree of harm.

Q. But they do exist?

A. They do exist in very rare circumstances.

Q. In this case, do you have an opinion as to any specific number of prescriptions for opioids filled in the Nassau or Suffolk County that were not for a legitimate medical purpose?

MR. ARBITBLIT: Object to form.

THE WITNESS: I do not have a specific number.

Q. BY MR. CARTER: Do you have a specific percentage?

MR. ARBITBLIT: Object to form.

THE WITNESS: Percentage wise, I would opine that the large majority of prescriptions written for opioids in Suffolk and Nassau County were not, in fact, written for legitimate medical purposes, but not because the physicians were -- were in any way practicing outside of what they had been taught. Let me rephrase that.

The majority of opioid prescriptions written in those counties, as sort of broadly representing the phenomenon in the United States, have been written for what doctors thought was a legitimate purpose, but in fact was not a legitimate purpose, that they were duped into believing that opioids are safe and effective treatment, when, in fact, they are not safe and effective for the purposes of chronic and minor pain conditions.

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Q. BY MR. CARTER: Were such prescriptions, as you described them, filled and dispensed by pharmacists acting in good faith?

MR. ARBITBLIT: Object to form.

THE WITNESS: I would really have to look at the specifics of the actions of a given pharmacy and a given pharmacist to be able to make that determination.

Q. BY MR. CARTER: And you have not done that work and therefore do not have any such opinion for this case. Fair?

A. Well, I do have an opinion, which I've expressed, but I haven't done that specific work on a specific pharmacy or a specific pharmacist in those counties.

Q. Sitting here today, can you tell me either a number or percentage of prescriptions for opioids that the pharmacy defendants in this case should have refused to dispense in Nassau County?

A. I think the way that you framed the question simplifies the problem. So it's not just a matter of pharmacists refusing to fill a prescription; it's a matter of pharmacists doing their due diligence to determine whether or not the risks outweigh the benefits for a given prescription. And I think in general, across the opioid supply chain, that kind of due diligence has been absent.

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Q. Let me reask my question.

Are you able to opine and provide either a specific number or a specific percentage of prescriptions for opioids that you believe a pharmacy defendant should not have dispensed in Nassau County?

MR. ARBITBLIT: Object to form.

THE WITNESS: I'm not able to provide a specific number or a specific percentage, but I have a qualifier, if that's okay.

But, again, I do think that it's not as simple as refusing to dispense. And a large part of my work, especially in the past three to four years, has emphasized the need for compassionate tapers. We have created several generations of individuals, pain patients who are now physiologically dependent on opioids and should not be abruptly discontinued.

So I think an effective intervention here is not simply to refuse to dispense, but it's to come together and figure out how we can safely and compassionately care for several generations of Americans who have suffered iatrogenic harm.

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Q. BY MR. CARTER: Sitting here today, are you able to provide an opinion regarding the number or a specific percentage of prescriptions for opioids that a pharmacy defendant should have refused to dispense in Suffolk County?
A. Same answer as before.
Q. Okay. Have you ever worked with Dr. Judith Prochaska?
A. Yes.
Q. Have you spoken to her about your testimony in this case?
A. Not at any level of detail.
Q. Have you spoken to her about testifying in trials on behalf of plaintiffs?
A. I may have mentioned that I've been retained as an expert witness, but not -- not any specifics beyond that.
Q. Are you familiar with Dr. Robert Proctor from the history department at Stanford?
A. Yes.
Q. Have you ever spoken to him about testifying for plaintiffs in litigation?
A. No.
Q. Okay. Have you spoken to him about your opinions and work in the area of opioids?

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A. No, I have not.
MR. CARTER: Those are all the questions I have, time permitting. I'll just note for the record I do have additional questions, but subject to the Court's limitations, I have to tender the witness at this time. So I just have an objection on that basis.
Thank you for your time, Doctor.
THE WITNESS: You're welcome.
THE VIDEOGRAPHER: Off the record again?
MR. CARTER: Yes, please.
THE VIDEOGRAPHER: Going off the record, the time is 1:15 p.m.
(Recess.)
(Mr. Pyser leaves deposition room.)
THE VIDEOGRAPHER: Back on the record, the time is 1:23 p.m.

EXAMINATION

Q. BY MR. TSAI: Good afternoon.
A. Good afternoon.
Q. Very good to see you again.
A. Likewise.
Q. One of these days we should chat more about your Chinese language skills.
A. Uh-huh.
Q. So just diving right in, have you ever been

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excluded by a Court from testifying as an expert regarding marketing causation? That is, any effect defendants' marketing efforts may have had on the supply or sales of opioids?
A. I do believe in the MDL it was determined that I do not have marketing expertise and so should not opine on direct causation, but I would qualify that by saying that I do have expertise on the extent to which scientific evidence has informed or failed to inform the marketing material of defendants in this case.
Q. And have you read the opinion excluding you from offering those opinions?
MR. ARBITBLIT: Object to form. Vague, "those opinions."
THE WITNESS: Yes. So could you --
Q. BY MR. TSAI: Those opinions that I've referred to, that you've agreed that you have been excluded from testifying as an expert about.
MR. ARBITBLIT: Object to form.
Do you have the order?
MR. TSAI: (Shakes head.)
THE WITNESS: So I guess could you repeat the question?
Q. BY MR. TSAI: Yes.
Have you read the order that you referred to the

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national MDL excluding you from testifying regarding marketing conditions?
A. Yes, I have read that order. But I would say that it --
MR. TSAI: You know, I think that we've got a limited time. Let -- the admonition directly from the Court is answer the question. Don't offer additional opinions. So I'd like to move on.
Q. Do you have any degrees or training in pharmacoeconomics?
A. No.
Q. Do you teach any courses on the econometrics of sales or marketing?
A. No.
Q. Do you have any degrees or training in the econometrics of sales or marketing?
A. No.
Q. Do you have any degrees or training in marketing statistics?
A. No.
Q. Do you have any employment experience working in the field of pharmaceutical marketing?
A. No.
Q. Do you belong to any professional associations in the field of pharmaceutical marketing?

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A. No.
Q. Have you ever worked for the DA?
MR. ARBITBLIT: The DA?
Q. BY MR. TSAI: DEA.
A. No.
Q. Have you ever consulted for the DEA?
A. I have done some unpaid consulting for the DEA.
Q. Oh. When was that?
A. That was just last week.
Q. Okay. And what was the nature of that consulting?
A. A DEA agent in Oakland who does undercover work to try to figure out whether doctors in that area are engaging in safe opioid prescribing consulted me about what an evidence-based evaluation of a patient should look like, and I spent about an hour on the phone with him.
Q. Okay. How many conversations did you have with that DEA agent in Oakland?
A. One.
Q. Okay. Other than that conversation, have you consulted for the DEA?
A. No.
Q. Have you ever designed a suspicious order monitoring program?

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A. No.
Q. Do you hold yourself out as an expert in the design or implementation of DEA registrant suspicious order monitoring?
A. I think that I could offer an informed opinion on what suspicious orders might look like based on my clinical experience and my knowledge of addiction.
Q. Do you consider that informed opinion to be expertise in the -- the design and implementation of a DEA registrant's suspicious order monitoring systems?
A. I think as a front-line clinician working with people with opioid addiction and as somebody who has researched the opioid epidemic, I could be a useful source of knowledge in designing such a system.
Q. Are you familiar with the concept of sameness in the context of sales of generic medicines?
A. If by "sameness" you mean that drugs are pharmacologically similar and act in a similar way. Is that what you mean by "sameness"?
Q. Is that your understanding of what that term "sameness" means in the context of generic medicines?
A. That would be my guess as to what it means.
Q. Are you aware that makers of generic opioids did not have a sales force for those generic medicines?
A. I am aware that makers of generic opioids did

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not have a specific sales force for their generics, but most of the opioid manufacturers' defendants in this case had a combination of branded and generic opioids, and the generic -- and the marketing that those defendants did for their branded opioids augmented sales and influenced sales in prescribing of their generic opioids.
Q. Are you aware of any -- can you identify any defendant maker of generic opioids with a sales force in New York?
A. I don't know specifics on their sales forces in New York. I would assume that all of the defendants have deployed a sales force in New York state.
Q. Sorry. I meant with respect to their portfolio of generic medicine specifically.
MR. ARBITBLIT: Object to form.
THE WITNESS: Could you rephrase your question?
Q. BY MR. TSAI: Sure.
Identify a defendant maker of generics that had a sales force for those generic opioids in New York.
A. I am assuming, although I don't know for sure, that all of the defendants had a sales force for opioids in the state of New York.
Q. And by "opioids," you're referring to a sales force for their branded products; correct?
A. Yes. But as I said, their marketing for branded

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products also impacted the sales of generics.
Q. You did no regression analysis to isolate the impact on sales that any opioid marketing by any individual defendant had on New York doctors and nurses; is that correct?
A. I did no personal regression analysis.
Q. Okay. You did not conduct any analysis to isolate which individual prescribers in New York purportedly relied upon any alleged marketing by any individual defendant; correct?
MR. ARBITBLIT: Object to form.
THE WITNESS: On a national scale?
Q. BY MR. TSAI: Again, answer the question. I limited this to New York.
MR. ARBITBLIT: Object to form.
THE WITNESS: I believe that most prescribers in New York were the recipients of the misleading promotional messages of opioid manufacturers in New York state, and I base that on my discussions -- I base that in part on my discussions with doctors in the state of New York in my travels there.
Q. BY MR. TSAI: You know, the directive from the Court is you must be direct and not evade, answer the question. Otherwise, we'll be back here.
So I asked you very specifically about New York

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and about individual prescribers and individual defendants. So let me ask again, and if I could please receive an answer to that question.

You did not conduct any analysis to isolate which individual prescribers in New York purportedly relied upon any alleged marketing by any individual defendant; is that correct?

MR. ARBITBLIT: Object to form and object to badgering and object to the precursor to the question.

THE WITNESS: I did not conduct individual analysis of specific prescribers in the state of New York.

Q. BY MR. TSAI: Did you conduct any actual survey specific to New York regarding pharmaceutical marketing that was seen or heard or otherwise communicated to doctors or patients in New York?

A. I have had discussions with doctors in the state of New York who have told me that they've been the recipients of the same misleading promotional messages as all the rest of us have for the past three decades and -- and also the statistics on addiction rates and deaths in the state of New York mean that New York is not somehow a exception on a national level in terms of this opioid epidemic.

And so that leads me to conclude that

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prescribers in the state of New York were also duped in terms of their understanding of the evidence base regarding the use of opioids in the treatment of pain.

Q. And that wasn't my question.

So you conducted no comprehensive survey of doctors and nurses in New York to understand what marketing materials, if any, prescribers in New York received from what individual defendant; is that correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: I feel like I answered your question to the best of my ability.

Q. BY MR. TSAI: So do you have a survey that you can show us where you surveyed doctors and nurses in New York regarding asking them for, for example, Mallinckrodt, what specific marketing materials did you, Dr. Smith in Nassau, receive from Mallinckrodt? Do you have that to produce?

MR. ARBITBLIT: Object to form.

THE WITNESS: I don't have a survey at that level of specificity.

Q. BY MR. TSAI: Okay. And just to confirm, even though you've deleted Purdue from your report in this case, in your opinion, do you still consider Purdue as a contributor to the opioid situation in New York?

A. Yes, I do.

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Q. Have you done any analysis yourself quantifying the contribution in your opinion of that company to the opioid situation in New York?

A. I have not quantified the contribution, nor do I think that it's my role to quantify the contribution.

Q. Okay. And you have not quantified the contribution, nor do you believe it's your role to quantify the contribution, with respect to any defendant in this case.

Is that fair to say?

MR. ARBITBLIT: Object to form.

THE WITNESS: Well, I would quantify -- I would quantify the contribution of the defendants in this case by saying that without their actions, I believe the opioid would not have occurred.

Q. BY MR. TSAI: Okay. So that's a general opinion as to all defendants as a group, fair to say?

A. That's correct.

Q. So just to be clear, you have not done any analysis yourself quantifying the contribution in your opinion of any specific defendant business to the opioid situation in New York; is that correct?

A. Yes.

Q. You believe that others, let's say outside the circle of what you say is the opioid pharmaceutical

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industry, others bear some responsibility for the opioid epidemic; is that correct?

A. That is correct.

Q. Okay. Can you show me where in your methodology you quantified the extent to which those other persons and entities bear responsibility for the opioid epidemic in New York?

MR. ARBITBLIT: Object to form.

THE WITNESS: I don't specifically quantify the responsibility of those other entities, but I do make it very clear that the opioid pharmaceutical industry, namely, the defendants, took advantage of some of the structural problems inside medicine to leverage their push for an increase in opioid prescribing.

And I do also make it clear that although others are responsible, without the actions of the opioid pharmaceutical industry, I do not believe this opioid epidemic would have occurred, whereas those other entities, their actions might still have occurred, and I don't think it would have led to the crisis that we have today.

In other words, the actions of defendants have been instrumental.

Q. BY MR. TSAI: So let me complete this concept.

So in your methodology, there is no place you

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can point to, for example, where you quantify the extent to which government policies caused or contributed to the opioid epidemic in New York.

Is that fair to say?

MR. ARBITBLIT: Object to form, misstates the record.

THE WITNESS: I don't specifically quantify, but I do a lot of qualitative analysis and have done qualitative analysis, both in the writing of my book and in forming my opinion. And in my qualitative analysis, I have apportioned responsibility, pivotal responsibility, to the actions of the defendants.

Q. BY MR. TSAI: But no portion of your methodology where you can point to where you quantify the degree of responsibility that you would allocate to government policies?

MR. ARBITBLIT: Object to form.

THE WITNESS: I don't give it a number, no.

Q. BY MR. TSAI: Okay. Same question with respect to the extent to which managed care or reimbursement policies caused or contributed to the opioid epidemic in New York.

MR. ARBITBLIT: Object to form.

THE WITNESS: I don't give it a number, no.

Q. BY MR. TSAI: Same questions with respect to

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quantifying the extent to which formulary coverage had an impact on the opioid epidemic in New York.

MR. ARBITBLIT: Object to form.

THE WITNESS: So again, all of those contributing factors that appear, as you were phrasing the questions, to be separate from the actions of the defendants were actually heavily influenced by the lobbying efforts of the defendants.

So it's difficult for me to isolate and quantify the contributing responsibility of those separate factors, when those factors are not, in fact, separate from the actions of the defendants. And I talk about that in my report.

Q. BY MR. TSAI: Okay. So, again, just to ask the question, I'm asking you to answer it.

A. Yeah.

Q. You did not isolate the extent to which, in your opinion, formulary coverage was responsible for the opioid epidemic in New York; is that correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: So I didn't isolate it because I don't believe it's isolateable. I believe that many of these structural factors inside and outside of medicine were, in fact, influenced by the opioid pharmaceutical industry.

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Q. BY MR. TSAI: Okay. You said many. I just want to be clear.

Do you believe that every factor that you have said others bear some responsibility for the opioid epidemic, every contributing factor is attributable to what you call the opioid pharmaceutical industry?

MR. ARBITBLIT: Object to form.

THE WITNESS: If not attributable, then actively exploited by the defendants to increase the supply of opioids.

Q. BY MR. TSAI: So let me just make the record and continue.

Is there any part of your methodology you can point to where you quantified the extent to which health insurance companies dictated whether and which patient was prescribed opioids and therefore contributed to the opioid epidemic in New York?

MR. ARBITBLIT: Object to form.

THE WITNESS: So in my report, I do reference an article on page 5 of the "Use of Opioid Agonist Therapy." And this article specifically looks at opioid prescribing among Medicare Part D patients and notes that at that time, Medicare Part D, for example, did not cover prescriptions for -- give me a moment -- methadone maintenance in the treatment of opioid use disorder, and

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that although Medicare Part D did cover buprenorphine/naloxone for the treatment of opioid use disorder, the whole message, or one of the major messages of that article was to opine on the fact that what a -- what a third-party payor like Medicare will cover does influence how that medication is prescribed.

Q. BY MR. TSAI: Okay. So let me switch gears and let me make it a little more interesting.

Let me ask you just agree or disagree, in your opinion.

So agree or disagree in your opinion with this proposition: Proper assessment of the patient, proper prescribing practices, periodic reevaluation of therapy, and proper dispensing and storage are appropriate measures to help limit abuse of opioid drugs.

A. Yes, those are appropriate measures, but probably not in and of themselves sufficient.

Q. Same question. Agree or disagree in your opinion with this proposition: Concerns about abuse, addiction and diversion should not prevent the proper management of pain?

A. Implied in your question is that the proper management of pain involves prescribing opioids, and I would say, especially when it comes to chronic pain, that is not true, and that the proper management of chronic

pain would be expressly to avoid the prescribing of opioids in the vast majority of cases. Because the evidence is very convincing that opioids used long-term don't work and may even make the pain worse.

Q. Okay. Just to clarify, let's talk about the specific context of prescribing an opioid for someone who is showing long-term pain, telling her doctor she has long-term pain.

In your opinion, would saying to a doctor, "Concerns about abuse, addiction and diversion should not prevent the proper management of pain," is that misleading, in your opinion?

MR. ARBITBLIT: Object to form.

THE WITNESS: Yes, that is misleading in my opinion, yeah.

Q. BY MR. TSAI: Okay. Agree or disagree in your opinion with this proposition: The potential for these risks of opioid addiction, abuse or misuse should not prevent the prescribing of opioids for the proper management of pain in any given patient?

MR. ARBITBLIT: Object to form.

THE WITNESS: I would really need you to qualify your question regarding more specifically the nature of the pain condition, the prognosis of the individual, whether opioids were being recommended for short or

long-term use.

But to more broadly respond, I do think that the risk of opioid addiction and misuse should be front and center in that healthcare provider's thoughts when considering an opioid prescription.

Q. BY MR. TSAI: So is it fair to say -- this is my understanding of your response, is that it depends on the clinical context, things like the nature of the condition, the prognosis of the specific patient, the type of opioid, whether it's short-term, long-term, to -- to opine whether that statement that I just -- that proposition that we just discussed, stating that to doctors would be improper?

MR. ARBITBLIT: Object to form.

THE WITNESS: So the list of topics that you listed are certainly important in the consideration of prescribing opioids, but are not in and of themselves sufficient.

The prescriber must also take into account the broader context of the problems of abuse and diversion, especially now in the United States, given the scourge of addiction and death, the opioid epidemic.

So it's not just the individual care of that patient, although very, very important. We also have to take into account the Public Health and population level

health. As well as -- as well as be able to form judgment for how to prescribe the opioid based on true and reliable scientific evidence.

Q. BY MR. TSAI: So let me just read that proposition again.

The potential for these risks of opioid addiction use or misuse should not prevent the prescribing of opioids for the proper management of pain in any given patient.

Do you think that that's an accurate statement?

MR. ARBITBLIT: Object to form.

THE WITNESS: Could you do me a favor? Because I want to make sure I accurately understand your question. Could you just say the proposition --

Q. BY MR. TSAI: Uh-huh, yes.

A. That you want me to --

Q. Yes.

A. Okay. Thank you.

Q. The potential for these risks of opioid abuse, addiction and misuse should not prevent the prescribing of opioids for the proper management of pain in any given patient?

MR. ARBITBLIT: Object to form.

THE WITNESS: I disagree with that.

Q. BY MR. TSAI: Okay. If it were up to you, would

you recommend that prescription opioid medications be taken off the market?

A. Of course not.

Q. Okay. Would you ban prescription opioids for all pain conditions?

A. Of course not.

Q. Would you ban the prescription of opioid medications for all pain conditions involving non-cancer pain?

A. Of course not.

Q. Okay. Would you recommend banning opioid medications for the treatment of conditions involving chronic non-cancer pain?

A. Of course not.

Q. Okay. So again, agree or disagree with this proposition: There are some people for whom chronic opioids for pain work?

A. I would say the scenario in which chronic opioids for chronic pain are more helpful than harmful is a very rare scenario, and in my professional experience, I have seen more harm than good come from chronic opioid therapy, plus the evidence does not support the use of opioids in the treatment of chronic pain. All reliable studies show that opioids are no better than Tylenol or Ibuprofen, with many more incurred risks, and that the

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risk of addiction and overdose death increases with increasing dose and duration of the opioid therapy.

Q. All right. This sounds a lot like commenting on something I didn't ask.

Let me ask you very quickly again, do you personally believe that there are people in the United States and New York for whom chronic opioids work, for which the benefit outweighs the harm?

MR. ARBITBLIT: Objection. And since counsel is insisting on putting his preface before the question, which is inappropriate, I'll put mine in, which is that you've answered the question. If you have anything to add, you're free to do so.

THE WITNESS: I do think I answered the question.

Q. BY MR. TSAI: So is it a "yes," there are people for whom chronic opioids work?

MR. ARBITBLIT: Object to form.

THE WITNESS: I am willing to consider the possibility that there is a very small group of individuals for whom the benefit of long-term opioids may be slightly better than placebo. But as time goes on, I think the incurred risks for the vast majority of individuals will outweigh any small, incremental benefit.

Q. BY MR. TSAI: Okay. Along this line, here's a

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slightly different question.

Do you agree or disagree in your opinion: The benefit of short-term opioid therapy is supported by multiple clinical trials?

A. So there are reliable trials showing opioids as effective in treatment very short term for acute pain. But there are also studies showing that even acute exposure can lead to significant harm.

For example, in my report, I cite a study by Shroeder, et al., showing that a single exposure to opioids through a prescription from a dentist for young people between the ages of 16 and 25, that approximately 6 percent of those individuals will go on to be diagnosed with an opioid use disorder within that year.

My point only being, to be able to answer your question completely, is that it's not as if the short-term use of opioids is an entirely benign and non-risky scenario.

Q. Let's talk about evidence. So do you -- in your opinion, is there enough evidence to support the use of opioids for some people presenting with chronic non-cancer pain?

MR. ARBITBLIT: Object to form.

THE WITNESS: No, there's -- there's not reliable evidence to --

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Q. BY MR. TSAI: I said evidence, just any evidence.

MR. ARBITBLIT: Counsel, don't interrupt her when she's answering. Just Calm down and don't interrupt her when she's answering. You can comment when she's done.

MR. TSAI: I just wanted to clarify.

MR. ARBITBLIT: You didn't want to clarify. You interrupted her.

Q. BY MR. TSAI: Since you interjected, I actually intentionally framed it broadly so I just want to point that out.

In your opinion, is there any evidence to support the use of opioids for some people presenting with chronic non-cancer pain?

MR. ARBITBLIT: Object to form.

THE WITNESS: I think there is some evidence that there is a very small benefit in some people with the use of opioids long-term, but most of the time that benefit does not meet a clinically meaningful threshold.

I talk about in my report, Busse does a metaanalysis looking at the efficacy of opioids long-term in the treatment of pain and finds that there is -- when all of that data is put together, no clinically meaningful difference for those individuals compared to a

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placebo and the risks incurred are obvious and great and dose-dependent, increasing with dose duration.

Q. BY MR. TSAI: So we've heard the term "evidence base," and I just want to see if we can clarify that for our jury. So let's give an example.

What if it works, opioid therapy works for Mrs. Smith on Long Island, and she's been taking it for several years, and it's proven to work in her case.

In your opinion, would that be an evidence-based case that chronic opioid therapy works for Mrs. Smith?

MR. ARBITBLIT: Object to form.

THE WITNESS: So that's a really loaded question because whether or not an opioid is working really depends on who you ask. And if you ask patients themselves, they will often endorse that it is working, when family members will report they're not getting out of bed, they're not engaging in family life, they complain that their pain is worse than ever.

So that -- I think therein lies the complexity of this, that to rely on a patient's subjective account alone is insufficient and often wildly inaccurate.

And I think the pain community in the United States has widely acknowledged that subject -- subjective reports of levels of pain is insufficient to assess the efficacy of opioids in the treatment of chronic pain.

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The entire field of pain in the United States has moved toward, for example, including function as well as reports of pain relief in that assessment.

The Kaiser Washington Post Family Foundation survey study cites that if you ask patients themselves with chronic pain, who are on long-term opioid therapy, whether or not they may be developing an addiction to that opioid, 30 percent will endorse that they're worried about that. But when you ask their immediate family members, 50 percent of their family members will endorse that they're worried about that.

So there's this important gap between the subjective experience of improvement and actual improvement, and that is because opioids don't just work on the new opioid receptor, they also work on the brain's reward pathway. So they're reinforcing for reasons that have nothing to do with pain.

Q. BY MR. TSAI: Okay. So I'm curious just to test that. The followup question, of course, is: What if not only Mrs. Smith herself, but also Dr. Jones, her doctor, and her family members observed that the chronic opioid therapy reduces her pain and does not have significant side effects.

In your opinion, would you advise discontinuing that course of therapy?

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MR. ARBITBLIT: Object to form. Incomplete hypothetical.

THE WITNESS: I think there are rare instances in which chronic opioid therapy for chronic pain may, in fact, provide some small benefit. But I would argue that even in that context, intense vigilance and monitoring is required and a constant reassessment of the risks, benefits and alternatives. Because at any point, that could turn south, and what was previously beneficial may not be.

But I also want to add to that, that the current standard of care and monitoring procedures are not in existence in this country right now, largely because of the actions of defendants that persuaded prescribers that they didn't really need to monitor because opioids were so safe and patients wouldn't get addicted and there are not problems and they work great and you can go as high as you want.

Q. So that intense vigilance and monitoring post prescription that you advise, who does that?

MR. ARBITBLIT: Object to form.

THE WITNESS: That vigilance and monitoring, we are all responsible for performing a level of vigilance and monitoring which is within our professional scope and domain.

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So that includes prescribers, that includes pharmacists, that includes pharmacies, that includes distributors, that includes opioid manufacturers.

Q. BY MR. TSAI: Includes the patients themselves?

A. It includes patients themselves.

Q. It includes family members of patients?

A. Although -- although I would say that patients themselves come to us vulnerable and seeking help, and we have a responsibility toward patients in pain, who are incredibly vulnerable in that circumstance.

They rely on us to care for them, and that is our responsibility. It is not their responsibility to figure out whether or not they've gotten addicted to an opioid.

Q. So I just want to be clear. So in your opinion, so let's say for Ms. Smith as an example. Is it your opinion that my client, Mallinckrodt, or another defendant should be responsible for monitoring the signs and symptoms of her post-prescription condition?

MR. ARBITBLIT: Object to form.

THE WITNESS: On some level, yes.

Q. BY MR. TSAI: What level?

A. Well, if you are getting reports, if -- if your client is getting reports that individuals are being harmed by opioids, becoming dependent, getting started

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and not being able to get off, engaging in obviously addictive behavior, you have a responsibility to the Public Health to do something about that.

Or if you are aware that the distributors that ship your pills to small communities are, in fact, distributing large volumes to tiny little towns that could never possibly need that many pills in a billion years, it's your responsibility to go to your distributor colleagues and say, you know, what's going on here.

Q. So a couple more questions about propositions I just want to get your opinion on.

What about this proposition: Abuse of opioids can occur in the absence of true addiction and is characterized by misuse for nonmedical purposes, often in combination with other psychoactive substances?

A. I'm sorry, it's not coming up on the screen the way you said it.

Q. I'll read the proposition again. And just tell me if you agree or disagree in your opinion.

Abuse of opioids can occur in the absence of true addiction and is characterized by misuse for nonmedical purposes, often in combination with other psychoactive substances.

A. I agree with that proposition.

Q. Yeah. What about this one: Abuse and addiction

are separate and distinct from physical dependence and tolerance?

MR. ARBITBLIT: Object to form.

THE WITNESS: I believe that the distinction that has been made between opioid addiction and opioid dependence is primarily one of convenience for defendants in this case, who tried to push the use of opioids to doctors and their patients by claiming that dependence in and of itself is a non-risky, non-harmful condition.

Q. BY MR. TSAI: So let me go back to that way I stated it.

Abuse and addiction are separate and distinct from physical dependence and tolerance. In your opinion, would stating that to doctors be improper?

MR. ARBITBLIT: Object to form.

THE WITNESS: I think that the division between dependence and addiction that was made with the DSM-5 and that is commonly taught is primarily an artificial distinction to account for our iatrogenic crisis, and that, in fact, the overlap between addiction and dependence and the changes that occur in the brain in those two conditions are characterized by significant homology or similarity.

Q. BY MR. TSAI: Okay. So you think it's artificial, but do you think it's misleading or

inaccurate?

MR. ARBITBLIT: Object to form.

THE WITNESS: I think the promotional messages, the teaching messages, the marketing messages of defendants in this case have been extremely misleading around dependence as a separate, distinct, and in their opining, non-harmful condition. Yes, I think that's been a very misleading and artificial construct.

But now that we're there, now that we have tens of millions of people who are dependent but not necessarily meeting criteria for addiction because the DSM-5 criteria made it very hard to diagnose addiction, raising that bar, now we owe it to individuals to also make this artificial distinction, to classify people as either meeting DSM-5 criteria for addiction or meeting dependence in isolation.

But phenomenologically, what's happening in the brain is probably very similar.

Q. Okay. Last one, I think.

Agree or disagree with this proposition: There is no intrinsic limit to the analgesic effect of hydromorphone.

MR. ARBITBLIT: Object to form.

MR. TSAI: I can spell it for you later.

THE WITNESS: This concept of no limit really

stems from the fact that people exposed to opioids long-term develop tolerance and so invariably need a higher dose to get the same effect.

So I believe that the intrinsic limit has to do with the damage incurred by going to higher doses.

Q. BY MR. TSAI: Okay. So that concept that I stated, in your opinion, would stating that to doctors be improper?

A. Yes.

Q. Okay. So you talked about you're not licensed to practice medicine in New York, but I just wanted to kind of ask the followup question: Have you ever treated any person in New York? And when I say "New York," I'm talking about the state and the particular counties at issue in this case.

Have you ever treated any person in New York for any medical condition related to opioids?

A. I sometimes have patients who see me in consultation in California who come from other states. I can't be -- I can't recall one having come from New York.

Q. Okay. And so just to be clear, throughout your career, since you've been licensed in, I think 1995, you've practiced in the state of California?

A. That's correct.

Q. Okay. Is your opinion in this case based on

evaluating the individual case of any specific person in New York with an opioid addiction or overdose?

A. I don't believe so, no.

Q. Okay. So in forming your opinion in this case, you did not review any individual medical record identifying any specific person in New York with an opioid addiction or overdose; is that correct?

A. That is correct.

Q. Okay. So, again, this is educating the jury. A medical record for a patient typically contains a section for that individual patient's medical history, for example; is that correct?

A. Yes.

Q. Okay. So, for example, a patient's medical record would have the information as to whether that person had something like a previous diagnosis of a substance use disorder or addiction; is that right?

A. It is well-known that the listing in the medical record of diagnoses of addiction, including opioid use disorder, undercount the actual cases. And the reasons for that are complicated, having to do with the lack of training in medical school and residency on how to diagnose addiction, as well as the enormous stigma associated with those diagnoses, making prescribers reluctant to put it in the medical record, even when they

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know that the diagnosis is present. As well as patients themselves being very reluctant to have that diagnosis in the medical record, even in cases when they're getting active treatment for opioid use disorder.

So -- so my point -- and this is, I think, an important one to answer your question as best I can -- is that when it comes to opioid misuse, overuse, and addictive use, the medical record is more often than not woefully incomplete.

Q. So other components of a medical record would be that doctors are trained to elicit, ask for, patients are asked for input, provide, include family medical history; correct?

A. Yes.

Q. Include medication history; correct?

A. Yes.

Q. Include treatment and diagnosis history; correct?

A. Yes.

Q. Include review of systems; correct?

A. Correct.

Q. And what does "review of systems" mean?

A. Review of systems is where you go through all the major organ systems to see if a patient is having a problem in another major organ system that may not be

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directly relevant to the reason they are presenting in your clinic, but is certainly relevant to their overall medical treatment.

Q. Okay. So last time we talked, you had said, you know, you'd been in practice since 1995, and I think you had estimated you've seen approximately 40,000 patients over the course of your career.

A. (Nods head.)

Q. I just want to ask: Do you have any update to that?

A. No.

Q. That remains your estimate of the number of patients that you've seen in your career?

A. Yeah.

Q. And over the course of your career, you have prescribed many different kinds of opioids, dating back to 1995; correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: Yes.

Q. BY MR. TSAI: All right. And you've actually prescribed nearly every kind of opioid; is that correct, to your patients?

A. I don't have a distinct memory, because it was more than 20 years ago now, of what opioids I prescribed. But I prescribed -- I was very junior. I was in my

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training and then I was in my residency. So I prescribed whatever -- whatever other people were prescribing, but certainly plenty of hydrocodone, oxycodone and fentanyl products.

Q. Okay. Do you have any basis to kind of not think that you prescribed -- let me just ask it direct.

Did you prescribe short-acting opioids?

A. Yes.

Q. Did you prescribe long-acting opioids?

A. Probably.

Q. Did you prescribe both branded and generic opioids?

A. Probably.

Q. Sitting here today, what is your best recollection of the highest dose of an opioid that you prescribed one of your patients?

A. I don't have a recollection of the highest dose that I prescribed. I can tell you some of the highest doses that I've seen in my patient population that others are prescribing, but I don't have a recollection.

Q. I just wondered if you remembered. What about -- I mean, you've estimated the number of patients you've seen. Can you estimate the number of times you have prescribed an opioid to one of your patients?

MR. ARBITBLIT: Objection.

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THE WITNESS: I really can't, and I continue to prescribe opioids now, although just buprenorphine in the treatment of opioid use disorder.

Q. BY MR. TSAI: Okay. Well, is it safe to say that since you've treated on the order of 40,000 patients, that the number of times you've prescribed an opioid to one of your patients is in the thousands?

MR. ARBITBLIT: Object to form.

THE WITNESS: I think that's probably fair.

Q. BY MR. TSAI: And to the best of your recollection, did you ever prescribe opioids to your patients in combination with other drugs, in situations where they were taking other drugs?

A. On the inpatient setting, there's hardly a patient who's just on one drug, so yes.

Q. I'd like those agree or disagree. So I'm going to go back to some more, but it's a different topic.

So agree or disagree in your opinion: In terms of the treatment of pain, using pain medicine, each individual's medication regimen should be personalized?

MR. ARBITBLIT: Object to form.

THE WITNESS: So, to me, that is a broad, sweeping question that I would be reluctant to agree or disagree on without specifics.

Q. BY MR. TSAI: So that affirmative statement "in

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the treatment of pain using pain medication, each individual's medication regimen should be personalized," you're not -- you're not comfortable agreeing with that?

MR. ARBITBLIT: Object to form.

THE WITNESS: I -- I agree that medical treatment should be personalized, but also needs to be considered in the broader context of a Public Health crisis.

Q. BY MR. TSAI: And in designing a medication régime, personalizing it for a patient, whose -- who does that?

MR ARBITBLIT: Object to form.

THE WITNESS: Well, that's a great question because in the past 30 years, it's mainly been your client who has designed that. The work of the defendants has been such a force in the way that pain is treated, from the Joint Commission to the Federation of the State Medical Boards to CME, that that protocol is largely the invention of defendants in this case.

Q. BY MR. TSAI: Here's another statement. Agree or disagree, in your opinion: Opioids vary greatly in their pharmacokinetic and pharmacodynamic profiles, which in turn are influenced by route of administration and individual tolerability.

MR. ARBITBLIT: Object to form.

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THE WITNESS: Opioids are similar and different in many ways. So there is variation between opioids in the pharmacokinetics and pharmacodynamics, depending upon the route of delivery. But there are universal themes for all opioids, including the way that they bind and stimulate the opioid receptor, as well as the way that they're rewarding in the dopamine reward pathway, contributing to their addictive potential.

Q. BY MR. TSAI: Okay. But ultimately, how about this statement: Comparing dosages across opioids and individuals is challenging.

A. Yes, I agree.

Q. Okay. How about this one: Physicians should individualize therapy based on a review of the patient's potential risks, benefits, side effects and functional assessments and monitor ongoing therapy accordingly.

MR. ARBITBLIT: Object to form.

THE WITNESS: I would qualify that by saying that statement is true, but only when informed by a good understanding of the evidence.

Q. BY MR. TSAI: Okay.

A. For the benefit and risk of opioids. And only when that monitoring is done at an appropriate level of vigilance to really be able to detect the harm.

And right now, we're not there in terms of the

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medical profession. We need much more robust training, and we need many more resources to create the kind of medical infrastructure to make sure that safe prescribing is happening and that benefits actually are outweighing the risks and helping people who have become physically dependent get off.

Q. Right. And so putting aside your view of the state of medical training in the United States, in terms of roles, do you agree that it is the role of the prescribing physician to weigh the risks and benefits of any pain medication when treating their individual patient?

MR. ARBITBLIT: Object to form.

THE WITNESS: Healthcare providers, physicians, nurse practitioners, other healthcare providers are not working in a vacuum. They have enormous pressures on them to practice according to protocols and algorithms implemented by a healthcare facility. There are other pressures that I've talked about in terms of patient satisfaction surveys, et cetera.

So, yes, a physician needs to exercise his or her best judgment, but that judgment needs to be informed by the evidence, and it must be taken into account that there are other pressures on physicians when it comes to which medicine they choose to prescribe.

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So it's not always in their autonomous control.

Q. BY MR. TSAI: Okay. Do you agree with this statement: Without more -- without detailed data describing the clinical context, in particular the severity of pain, it's difficult to accurately determine medical appropriateness with respect to a prescription for any given patient?

MR. ARBITBLIT: Object to form.

THE WITNESS: I disagree with that statement.

Q. BY MR. TSAI: Okay. Well, can we agree that physicians in New York appropriately prescribed opioids in at least some circumstances?

A. That's a big blanket statement that I would be reluctant to agree to.

Q. Is it your opinion that all doctors throughout the state of New York who wrote prescriptions for opioid medicines for their patients did so inappropriately?

A. The vast majority, yes.

Q. Okay. The vast majority is different from all.

A. Uh-huh.

Q. Can you quantify it?

A. There may be some rare instances in which opioid prescribing was appropriate, but in the vast majority, I and my medical colleagues across the country, including the state of New York, have been describing opioids at

way too high doses for way too long.
Q. Well, we're going to be spending a lot of time at trial, including the jury. So can you put a number on that?
MR. ARBITBLIT: Object to form.
Q. BY MR. TSAI: What, in your opinion, the percentage of prescriptions by doctors in New York to their patients that, in your opinion, were medically inappropriate?
MR. ARBITBLIT: Object to form.
THE WITNESS: I have seen in my clinical experience no cases of opioids at high doses for long duration in which the benefits outweighed the risks, and I've seen a lot of patients in my career.
Q. BY MR. TSAI: Yeah. So your answer, I just heard, is your practice, and that's in California. This case is in New York.
So just to be clear: Is your opinion in this case based on reviewing any document enabling you to identify a single actual doctor who prescribed a single actual opioid pill to a single actual individual in New York?
MR. ARBITBLIT: Object to form. Objection to the prologue.
THE WITNESS: I am aware of lay press reports of

single individual doctors who prescribed single actual opioid pills to single actual individuals in New York, who were engaging in egregious overprescribing.
Q. BY MR. TSAI: So these are reports in the newspaper about pill mill doctors in New York?
A. That's right.
Q. Okay. Other than that, can you give -- identify any doctor who prescribed opioid medications to any individuals in New York?
A. No.
Q. Okay. Did you, in forming your opinion, ask for information from the New York counties or from the New York State regarding prescriptions that they determined were medically improper?
A. Well, I have reviewed data on New York prescribing, and it is here in my report. I refer you to page --
Q. Yeah, I think I know what you're -- it's the Nassau County data prescribing data that you referenced.
A. That's correct.
Q. Okay. So my question was a bit different.
So just let me ask this: Is your opinion in this case based on identifying concrete examples of specific prescriptions of any opioids written in New York that you believe, in your opinion, were medically

unnecessary or inappropriate?
A. My opinion is not based on specific prescriptions. It's based on aggregate prescriptions.
Q. Okay. Have you, in your practice, prescribed any medically inappropriate prescriptions of opioids to any of your patients?
A. Can you define "medically inappropriate"?
Q. I'd like to hear your definition.
A. Well, I think there are a couple ways to think about how to define that. Medically inappropriate might be a scenario in which I know it's not the right prescription for my patient and I prescribe it anyway. And I have never engaged in that kind of practice.
But another form of medical inappropriateness is where I believe that it's the appropriate prevention, but I'm wrong. But based on my belief, I prescribe the prescription -- I prescribe that medication for my patient. I have engaged in that kind of error in my -- in my career, yes.
Q. So taking that definition, using that one.
A. The latter one?
Q. The latter one, yes. How many times have you prescribed a medically inappropriate prescription of an opioid to your patients?
A. Well, as I testified previously, in the late

1990s -- well, throughout the 1990s in my medical school and residency training, I was engaging in inappropriate opioid prescribing on a regular if not daily basis. Because I was prescribing in a way that was informed by the misleading promotional messages of defendants, and the entire healthcare system at that point was hijacked by Pharma.
Once I became a psychiatrist, opioid prescribing was out of my scope of practice, although pain treatment was not. And then as I became more knowledgeable and more invested in helping patients who had become dependent or addicted to opioids, patients struggling with chronic pain, and I began to research this area, I got a courtesy faculty appointment in Stanford Department of Pain Medicine, began to see patients in their clinics, and then got the x-waiver certification to prescribe buprenorphine for opioid addiction, then I resumed opioid prescribing.
And in that context, I have made errors in opioid prescribing, but I like to think those errors have been few.
Q. Umm --
A. So well-intentioned errors, prescribing. An example might be thinking that a patient could steward a seven-day supply of buprenorphine and discovering by

urine drug screen or prescription drug monitoring database seven days later that no, in fact, they could not.

Q. Okay. So let's talk about that example. So that's an example of diversion; right?

A. Not necessarily. So diversion means that -- as you know -- just clarifying for the jury -- that the pills make it to someone other than for whom they were intended. But a very common problem that can arise is that patients misuse their own opioid prescription.

So most of the time in my clinical population, it's their personal misuse of the prescription rather than diversion, per se.

Because I can tell you most patients don't admit to diversion unless it's been years in the past. I have -- I have had patients tell me about their diversion activities, but usually not when they're under my care and not with my prescription. They don't do that.

They'll in -- in the process of recovery, talk about prescriptions they received from another provider in the past and diverted, which has been a good education for me about diversion.

Q. Well, can we agree that not every single opioid medicine that one of the defendants made was diverted to an illegal use?

A. Yes, we can agree.

Q. Can we agree that not every single opioid medicine that the defendant businesses made caused someone to become addicted?

A. Yes, we can agree to that.

Q. Okay. So you talked previously about examples, instances in your practice where you realized that your patients were giving away the opioid that you had prescribed them to, you know, third parties, like friends, family, to whom you did not prescribe the opioid; is that right?

A. Well, I want to qualify that answer. I think I would sharpen the accuracy of my response on that to say -- and I did try to do this a little bit earlier in the deposition -- that I have suspected in some rare cases that diversion was occurring and made adjustments accordingly, but it is not my clinical experience that patients will openly admit to diversion such that it becomes an obvious situation for involving, you know, criminal justice, and that most of my knowledge from patients about the diversion activities is diversion that they have engaged in in the distant past, after they're already in recovery.

Q. So these suspicious cases, for example, you would get a tox screen that was inconsistent with

properly using what you had prescribed; is that --

A. Yes.

Q. Okay. So in -- and can you give a number as to how many suspicious cases you -- over the course of your career, that you've encountered in this way?

A. I really can't give a number based on my personal experience. I don't tend to count like that, and I wouldn't want to give you a number that was inaccurate.

Q. Well, could we say more than ten?

MR. ARBITBLIT: Object to form.

THE WITNESS: More than ten individual cases of diversion?

Q. BY MR. TSAI: Where you suspected diversion in your patients?

A. We could probably say more than ten, yes.

Q. More than a hundred?

A. No, I wouldn't say more than a hundred.

Q. Okay. So when you had -- you suspected diversion, how did you -- tell me how you acted to counteract that suspicion, to counteract what you believe was diversion?

A. So I also want to qualify my prior statement regarding your attempts to quantify my patient experience around diversion.

Diversion is not something that I was even aware of or looked for or was trained to look for in medical school or residency. So in the '90s and early -- in the '90s, when I was prescribing opioids as part of my role as a resident or a physician in training, I didn't even know what diversion meant. Didn't have the first concept about it.

It's really only since I've become an addiction medicine specialist and I'm now running a clinic that I appreciate what diversion is and have a checks and balances in place to monitor, to the best of my ability, what diversion is all about. And I attribute that to the lack of proper training that I got in this regard.

So, sorry, I just wanted to qualify that.

Q. So among the checks and balances, for example, did you cut off the -- stop the prescription to that particular patient? I just want to know what you do.

A. Yeah. So it depends on the individual patient. And again, these aren't obvious cases of diversion where these -- you know, these aren't like people who are running a drug business. This is most often -- or I would say all of my patients who I am aware of may have engaged in some level of diversion, I had a suspicion for it. It was not confirmed.

But the first order of business is to discuss

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with the patient that I'm concerned about diversion or misuse, to ask them whether or not they can verify that that behavior is happening.

Patients will typically -- will often admit to a misuse problem. Will not typically admit to a diversion problem.

And then what I will typically do is talk about alternative treatment strategies. You know, this is not working for you. We need to think of a higher level of care or another intervention of some sort. And there are myriad treatments for opioid addiction.

So I will then begin to steer them in that direction.

Q. Okay. So in any of these, say, double-digit instances where you suspected diversion, did you need Mallinckrodt or any defendant to detect and counteract that diversion for your patient?

MR. ARBITBLIT: Object to form.

THE WITNESS: I mean, Mallinckrodt is the reason that, you know, the opioid epidemic, this problem is on my doorstep in the first place. Without Mallinckrodt, I probably wouldn't be an addiction specialist.

Q. BY MR. TSAI: I'm talking about your checks and balances for your patients. Did you call Mallinckrodt and did you need them to do that?

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MR. ARBITBLIT: Object to form.

Q. BY MR. TSAI: To take that action?

A. To take what action?

Q. To detect the addiction of your patient and then to take an action to check and balance that?

MR. ARBITBLIT: Object to form.

THE WITNESS: That would be great if Mallinckrodt wanted to get involved in creating an infrastructure to help with that. I think that isn't beyond the scope of what might be reasonable for somebody who manufactures opioids.

Q. BY MR. TSAI: I'm saying in your history, you had this practice, you had these patients --

A. Yes.

Q. -- was Mallinckrodt involved, any defendant?

MR. ARBITBLIT: Object to form.

THE WITNESS: Not directly involved, but indirectly involved in the way I described.

MR. ARBITBLIT: Let's take a break.

MR. TSAI: Okay.

THE VIDEOGRAPHER: Going off the record, the time is 2:31 p.m.

(Recess.)

THE VIDEOGRAPHER: Back on the record, the time is 2:48 p.m.

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Q. BY MR. TSAI: So let's take -- take up where we were talking about, so let's take the example of one of your actual patients, you had a suspicion that he or she was diverting the opioids that you had prescribed. For example, you did a urine tox screen, it wasn't consistent with his taking the regimen.

In any of those instances where you suspected diversion, did you report that to the police or any other -- any other authority?

MR. ARBITBLIT: Object to form.

THE WITNESS: So the suspicion for diversion when a urine drug screen is negative must be included in the differential diagnosis for that negative drug screen in a patient who's being prescribed an opioid. But it's not the only thing that may be going on.

As I said before, it could be an honest error. It could be an inaccuracy in the drug test itself, necessitating confirmatory testing in some cases. It could be even misuse on the part of that individual, for example, taking more of the drug than prescribed and then running out early, and hence not having any drug in their system at the time.

So I have never been in a situation where my threshold of suspicion regarding diversion was enough to motivate me to involve anybody else except for the

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patient and their immediate team, in some instances, including family members, and also to prompt me to change my care of that individual.

Q. BY MR. TSAI: Okay.

A. So I always do something.

Q. Yeah.

A. But I have never been in a situation where the -- the -- I was so convinced that diversion was occurring that I then felt it needed to be reported to an outside entity.

Q. Okay. So in other words, the suspicion of illegal diversion could be a false positive?

A. That is true.

Q. All right. It is not easy to ascertain whether a suspicion of diversion, in fact, equals actual illegal activity. Agree?

MR. ARBITBLIT: Object to form. Object to form.

THE WITNESS: You'll note that I said that even in the absence of knowing for sure whether diversion is taking place, I assume on some level that it could be and I take action in response. And that's very important piece, that I don't say, oh, well, it might be happening, but I'm not sure so I'm just going to continue business as usual. I don't do that.

Q. BY MR. TSAI: So in that example, at the ground

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level when you had a suspicion of diversion, Mallinckrodt or any of the defendant business -- businesses, they wouldn't have known about that situation because you didn't report it out.

Do you agree?

MR. ARBITBLIT: Object to form.

Q. BY MR. TSAI: That particular instance of suspected diversion?

MR. ARBITBLIT: Object to form.

THE WITNESS: Mallinckrodt would not have known about that suspected diversion necessarily unless that diversion was happening at such a high rate among so many providers that it was contributing to a serious Public Health problem in my community, at which point the death and addiction statistics should be sufficient to alert Mallinckrodt that a diversion problem is taking place.

Q. BY MR. TSAI: So in that instance -- let's talk about this example of your actual patient -- you agree you were in a better position compared to a Mallinckrodt or any of the other defendant businesses here to detect that instance of diversion?

MR. ARBITBLIT: Object to form.

THE WITNESS: I think you could make the opposite argument, that, in fact, Mallinckrodt, which has access to the ARCOS database that I, an individual

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front-line clinician don't have access to and don't know about, would be in a better position to detect population level diversion than I as an individual practitioner might be.

Q. BY MR. TSAI: I didn't ask about population. I'm saying Bob Chen, your patient who had failed his tox screen, and you didn't report that out to anyone, how would Mallinckrodt, in that example, know that there was diversion going on?

MR. ARBITBLIT: Objection. Form.

Q. BY MR. TSAI: Can you explain?

A. I think I did explain. I think I gave an answer to that.

Q. No, that example, that they know in that.

Your opinion -- you're telling the jury you believe Mallinckrodt should have known that Bob Chen failed his tox test even though you didn't report it out to anyone. I just want to see if that's your opinion.

MR. ARBITBLIT: Object to form.

THE WITNESS: My opinion is broader than what you're trying to get me to agree to, and that's why I'm not willing to agree to it.

My opinion is that Mallinckrodt and other defendants had access to population-level data that could have informed -- that did inform their knowledge of

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adverse consequences due to prescription opioids that they should have and could have acted on, but they did not act on, and that they, in fact, are better equipped to do that than I, an individual practitioner, who is only seeing this isolated instance of this one patient and may not have an aggregate sense of what's happening in the community.

Q. BY MR. TSAI: Well, the population, whether it's five or ten or a hundred, is made up of individuals; right?

MR. ARBITBLIT: Object to form.

THE WITNESS: (Nods head.)

Q. BY MR. TSAI: Okay. So is that a "yes"?

A. A population is made up of individuals.

Q. Okay. So can you explain to me in this example, how you believe any defendant could have or should have known about this instance of diversion?

MR. ARBITBLIT: Objection. Asked and answered badgering, redundant.

THE WITNESS: Yeah, I feel like I -- I answered the question at the level that it needed to be answered.

Q. BY MR. TSAI: Okay. What about for this individual?

MR. ARBITBLIT: Object to form.

Q. BY MR. TSAI: Because that's the level I think

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it needs to be answered.

A. Uh-huh.

Q. Okay?

A. Yes.

MR. ARBITBLIT: Object to form.

THE WITNESS: But it's a hypothetical situation. First it was Mr. Smith and then it was Mr. Chen.

Q. BY MR. TSAI: Yeah. And the order from this Court is that assumptions based on facts -- your Interrogatory, that's when we asked you to assume is true -- you have to answer. So let's focus on that.

I assume that Mr. Chen, your patient, failed his urine tox test. You did not report it out to anyone. You suspected that he was criminally diverting it by selling it, giving it to people who -- who shouldn't have gotten it.

Explain to me in that concrete example, given that hypothetical you have to assume is true, how any of the defendant businesses would be able to detect that diversion?

MR. ARBITBLIT: Objection. Incomplete hypothetical.

THE WITNESS: Again, I feel like I answered it. Although the defendants may not have been aware of that individual isolated case of mine -- I concede that to

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you -- they had been aware on an aggregate level of the harm due to the oversupply of opioids, including the problem of diversion, and yet they did nothing about it.

Q. BY MR. TSAI: So let's go back to the agree or disagree. I have some other propositions.

Agree or disagree in your opinion: Patients for whom chronic opioid therapy are being considered should be screened for risks and contraindications.

A. There is no evidence that screening patients prior to initiating opioid therapy reduces their risk of developing an opioid use problem. We do not have good screening tools. So hypothetically, it makes sense, if we could parse out those 30 percent of individuals who's going to develop an opioid use problem from the rest, that would be great, but we don't have the tools to do that.

And in educating physicians that screening actually worked, that was another form of misrepresenting the evidence.

Q. So just to be clear, in your opinion, would stating that proposition to practitioners, "patients for whom chronic opioid therapy is being considered should be screened for risks and contraindications," be misleading?

A. I think it's -- I think it's misleading because it's incomplete.

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Q. How about this one: Before initiating chronic opioid therapy, physicians should take adequate time to inform patients in simple language of the associated risks?

A. Yes, I agree with that.

Q. Okay.

A. Assuming that that physician is properly educated on what those risks are.

Q. Okay. How about this one: Patient education can help curb opioid misuse and reduce the risk of developing opioid use disorder?

MR. ARBITBLIT: Object to form.

THE WITNESS: I don't think that we don't have good data to show whether or not educating patients will actually curb their risk of opioid misuse. I think it's a logical assumption, but it's not actually been proven to be the case, and I can tell you that the way that opioids working on the brain is that they are reenforcing beyond what the patient may understand about their risks.

So it's a logical proposition, but I don't believe there's evidence to actually show that educating patients about the risks reduces their chances of developing opioid use problem.

Q. BY MR. TSAI: Okay. So then just to be clear: Do you believe stating that proposition would be

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misleading to practitioners?

A. Yeah, I think that would be misleading.

Q. What about this one: Physicians should also perform ongoing risk-benefit assessments throughout the course of therapy because problems can arise at any point?

A. Yes, I would agree with that.

Q. Okay. How about this one: Patients should be reevaluated at least every three months, even when stable and doing well, and more frequently if problems arise?

A. Yes, I agree with that.

Q. Okay. How about this: The risk for opioid abuse is increased in patients with a personal or family history of substance abuse, including drug or alcohol abuse or addiction, or mental illness, for example, major depression?

A. Yes, I agree with that.

Q. Okay. Agree or disagree in your opinion with this proposition: Patients at increased risk may still be appropriately treated with modified-release opioid formulations, however, these patients will require intensive monitoring for signs of misuse, abuse or addiction?

MR. ARBITBLIT: Objection.

THE WITNESS: Can you restate just because the

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transcription is not accurately represented. It says "real estate" opioid formulation. So would you repeat?

Q. BY MR. TSAI: Okay. What about this proposition: Patients at increased risk may still be appropriately treated with opioid medications; however, these patients will require intensive monitoring for signs of misuse, abuse or addiction?

MR. ARBITBLIT: Object to form.

THE WITNESS: I think it's really important to qualify whether we're talking about short-term opioid therapy or long-term opioid therapy because the risks really diverge there.

I do agree that even patients with addiction may at times need a short-term course of opioid therapy for pain and that those individuals are at increased risk. But it's also true that per Edlund, the risk of developing opioid use problem -- the greatest risk factor is actually dose and duration of the opioid -- the higher the dose, the longer the patient's on it, and that that risk outweighs any personal or family history of an opioid use problem.

Q. BY MR. TSAI: So let's specifically substitute in an extended-release opioid medication. If we put that in, patients at increased risk may still be appropriately treated with an extended-release opioid formulation,

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would you agree or disagree with that?
A. Can you say the whole proposition again?
Q. Yeah.
Patients at an increased risk may still be appropriately treated with extended-release opioid formulations; however, these patients will require intensive monitoring for signs of misuse, abuse or addiction?
MR. ARBITBLIT: Object to form.
THE WITNESS: I think there would -- and when you say extended release, you mean short-term, long-term opioid therapy. I'll object because --
(Interruption in proceedings.)
MR. TSAI: Someone's -- I think someone's not on mute. We can hear you.
THE WITNESS: Yeah. So in general, I don't agree.
(Interruption in proceedings.)
THE WITNESS: So I don't believe that opioid long-term opioid therapy is --
(Interruption in proceedings.)
THE REPORTER: Can we go off the record?
THE VIDEOGRAPHER: Going off the record, the time is 3:02 p.m.
(Discussion off the record.)

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THE VIDEOGRAPHER: Back on the record, the time is 3:03 p.m.
Q. BY MR. TSAI: Okay. Do you agree that risk factors for opioid addiction other than mere exposure exist?
A. Yes.
Q. Okay. Is one of those risk factors for opioid addiction a personal history of a substance use disorder?
A. Yes.
Q. Okay. Same question for family history of a substance use disorder.
A. Correct.
Q. Same question for a history of doctor shopping.
A. Yes.
Q. Same question for a history of seeking early refills.
A. So in general, doctor shopping and early refills is highly correlated with prescription opioid misuse, and prescription opioid misuse is highly correlated, predictive of developing an opioid use disorder. So, yes. Whether it's a causative or a risk factor, but yes.
Q. Okay. Same question: Preadolescent history of sexual abuse is also a risk factor for opioid addiction.
A. Childhood trauma in general is a risk factor for many medical conditions, including mental health

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conditions, including addiction, yes.
Q. And psychiatric comorbidities is also a risk factor.
A. Yes.
Q. That's a big term, big mouthful. Can you explain to the jury what that means?
A. That means an individual who has a psychiatric disorder other than the disease of addiction. So that would include everything from major depression to obsessive compulsive order to bipolar disorder to schizophrenia.
Q. Okay. So given all these risk factors, do you agree that healthcare providers should assess each individual for opioid risk based on specific factors?
MR. ARBITBLIT: Object to form.
THE WITNESS: Healthcare providers should assess risk factors for opioid addiction informed by the knowledge that patients who screen positive for those risk factors are not the only patients who are at risk for developing opioid use problems, and that, in fact, our screening tools are not effective at predicting who will and will not develop an opioid use disorder.
So although we have no predictive tools, I nonetheless do endorse screening for those risk factors as part of a complete medical exam.

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Q. BY MR. TSAI: Okay. So can we agree that all things being equal, a person with either active or a history of substance use disorders is a higher risk candidate for opioid therapy than a person with no past or current history of substance use disorders?
A. I'm not sure we actually can agree to that because although we can look at large populations and see who has an opioid use disorder and see who has those risk factors and note higher prevalence of those risk factors in patients who develop an opioid use disorder, we still do not as of yet have a clinical predictive tool that will allow us to screen for anything in order to be able to separate who will and will not develop an opioid use disorder.
The bottom line importantly being that even patients with none of those risk factors can develop an opioid use disorder, period.
Q. How about this: Patients who are prescribed opioids are not all at equal risk for developing opioid addiction?
A. Patients who are on higher doses for longer duration are at increased risk of developing opioid risk disorder. Patients who have some of the risk factors you've mentioned, like co-occurring psychiatric disorders, are at increased risk of developing opioid use

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disorder, but the relative risk of dose and duration outweigh the risks of those other -- those other risk factors.

Q. And the dose of an opioid medication for a particular patient can change over time. Agreed?

A. In fact, it typically does change over time as patients develop tolerance, given the way that we've been practicing, to respond to tolerance by increasing the dose, given the way that we have been miseducated to believe that quote/unquote no dose is too high.

Q. And it's the doctor who decides what dose of an opioid medication his or her individual patient receives, when prescribed, and over the course of treatment.

Do you agree?

MR. ARBITBLIT: Object to form.

THE WITNESS: Yes and no.

Q. BY MR. TSAI: Who else decides -- who else decides the dosage regimen of a particular doctor's particular patient?

A. So the amount and duration and choice of the opioid is heavily influenced by things like what's on the pharmacy formulary for a given hospital or what that patient's insurance will cover or whether or not the Joint Commission infiltrated that hospital and said you'd better, in so many words, prescribe opioids to any

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patient that endorses pain above a given level.

Or in a situation where a patient has demanded a certain opioid prescription and rated that -- that doctor poorly because of it or in a situation where that patient -- that doctor may be afraid that they will get sued or lose their medical license if they don't do everything in their power, i.e., prescribe an opioid to treat that patient's pain.

So lots of invisible forces inside of medicine driving prescribing, which the defendants in this case well understood and exploited in order to promote their products.

Q. Let me ask you this, and this is a hypothetical: So let's assume the same dose and duration for Mrs. Smith and Mr. Chen, same dose and duration. Mrs. Smith has never been depressed, never taken drugs before, never had a family member who took drugs, has a high-paying job, and then took an opioid medication for a legitimate pain condition.

In your opinion, would Mrs. Smith have the same risk of addiction as someone, call him Mr. Chen, with a long history of severe depression, history of prior illicit drug use, family history of drug use, unemployed, and who was doctor shopping?

MR. ARBITBLIT: Object to form.

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THE WITNESS: So you've asked me a hypothetical so I'm going to answer by talking about how I practice. Because we're not talking about a specific patient.

And the way that I practice, which I think is informed by the evidence and many years of clinical experience, is that any patient, regardless of those -- having or not having those risk factors, is at risk for developing an opioid use problem. And so I treat all of my patients the same in that regard, with the same level of caution and the same level of monitoring and vigilance.

Q. BY MR. TSAI: And you say "at risk." My question is in that scenario, comparing those two individual patient cases, is it your opinion that they have the same risk, different risk? What is that? What is your opinion on that? Not at risk, but the degree of risk.

A. So when we're talking about clinical care and I'm sitting in my office dealing with real, live patients, I fully acknowledge that I have no crystal ball for being able to determine who will and will not develop an opioid use problem.

I have seen many patients like your hypothetical Mrs. Smith, high functioning, well educated, high-paying job, no core current mental illness, no history of

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substance use problems, who goes on to very quickly develop an opioid use disorder in the context of receiving a prescription from a doctor.

Likewise, I have seen patients like your hypothetical Mr. Chen -- depressed, unemployed, doctor shopping -- who doesn't develop an opioid addiction.

So when we're talking about the level of clinical care -- not population-level studies, but clinical care and my ability to prognosticate, I assume I have zero ability to do that.

Q. Okay. So that -- now you kind of reversed. First you were in population mode and --

A. Yep.

MR. ARBITBLIT: Ask a question, Counsel. Don't lecture.

Q. BY MR. TSAI: So let's talk about population level.

MR. ARBITBLIT: Don't lecture the witness, Counsel. Ask a question.

Q. MR. TSAI: Do you have an opinion as to the relative degree of risk on a population level, given that scenario?

A. So I cite Edlund in my report. On page 20.

Q. So we're on the same page --

A. Yeah.

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Q. -- in terms of interpreting reading Edlund, you agree that Edlund was a -- was a study about associations, not --
A. Uh-huh.
Q. -- not causal relationships?
MR. ARBITBLIT: Object to form.
THE WITNESS: I agree that Edlund talks about risk factors in a population of individuals who were exposed to opioid therapy versus not.
Q. BY MR. TSAI: Okay.
A. I'm trying to determine the risk of individuals, the odds ratio of developing an opioid use disorder based on a certain type of risk factor.
I'm looking for another place that I cite Edlund in my report. Give me a moment, please.
Q. Okay. I don't want to spend too much time --
A. Okay.
Q. -- given our limited time. So --
A. I did -- I did find it.
If you'd like me to refer to it, page 73.
Q. Okay. Thank you.
A. The Edlund study.
Q. So did you do -- so other than the risk -- the several risk factors for opioid addiction that we've discussed, any others?

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MR. ARBITBLIT: I don't think she had finished answering the question when she referred to Edlund. You interrupted her.
THE WITNESS: Do you want me to finish answering your other question?
Q. BY MR. TSAI: Actually, it seemed like you were talking about something a bit different so let me just ask you this: In terms of the several risk factors out there, with respect to opioid addiction did you do any analysis of your own in your work in this case to quantify the contribution of these risk factors to opioid addiction in New York specifically?
MR. ARBITBLIT: Object to form.
THE WITNESS: I do not any of my own analyses, but as per my report, including on page 73, Edlund did quantify these risk factors, stating that for chronic high-dose opioid use, the odds ratio of approximately 122 is 40 times greater than for a mental health or alcohol use disorder and 15 times higher than for a prior non-opioid-use disorder.
In other words, the chronic use of opioids is responsible for far more opioid use disorders than the existence of identifiable risk factors for opioid use disorders.
Q. BY MR. TSAI: And when Edlund himself says

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information on how average daily dose and duration of opioid therapy may supply likelihood of development of an incident of opioid use disorder is limited, do you have any reason to dispute that conclusion by the study authors?
A. Where is that? Where is that?
Q. Page 2 of Edlund, 24.
MR. ARBITBLIT: Do you have the article?
MR. TSAI: I think she's looking at it.
THE WITNESS: No, I don't have the article. I just have my reference.
Q. BY MR. TSAI: Okay. Let's move on.
So do you agree or disagree with this statement --
(Discussion off the record.)
MR. TSAI: Let me go off the record real quick.
THE VIDEOGRAPHER: Going off the record, the time is 3:18 p.m.
(Exhibit 7, Pre-roll: Mischa intro, marked for identification.)
(Discussion off the record.)
THE VIDEOGRAPHER: Back on the record, the time is 3:20 p.m.
Q. BY MR. TSAI: So I just wanted to ask you about this interview that you gave. This -- I handed you

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Exhibit 7, which is entitled "Science Versus," from Gimlet Media with Wendy Zukerman. The program is entitled "Opioids, Kicking America's Addiction."
Do you recall giving interview for this program?
A. Not specifically.
Q. Okay. Can you refer to page 4? And I'll direct you to the very top of page 4. And it says: "Anna Lembke, a psychiatrist at Stanford, was one of those doctors who wasn't keen to treat addicts."
Do you see that?
A. Yes.
Q. And do you see the abbreviation "AL" henceforth under that?
A. Yes, I do.
Q. Okay. Is "AL" you?
A. Yes.
Q. Okay. And does this appear to be a correct transcription of your interview for this program?
A. Yes.
Q. Okay. I just wanted to quickly ask you about on page 11, there is a series of footnotes. Number 15 -- 52, sorry, states in email, "Don't let anyone tell you taking a medication is swapping one addiction for another. It is complete nonsense."
And the -- that corresponds to a sentence in the

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text saying, "Here's how Anna and other experts think about it."

Do you see that?

A. Yes.

Q. Okay. Do you know if you still have that email?

MR. ARBITBLIT: Object to form. That's misrepresenting the evidence.

THE WITNESS: I have no idea.

MR. ARBITBLIT: It doesn't link this to Anna in any way.

Q. BY MR. TSAI: Is it your understanding that you sent Wendy Zukerman an email with this statement?

A. I don't have a recollection of having sent that email, no.

Q. Okay. Okay.

So you can put that aside.

A. Okay.

(Exhibit 8, Handwritten notes, 1/16/14, marked for identification.)

Q. BY MR. TSAI: So I believe we talked about this at the last deposition, but this is -- I'm handing you what you produced when we requested your -- your notes in connection with writing your book --

A. Uh-huh.

Q. -- Drug Dealer, M.D., do you recall that?

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A. Yes, I do.

Q. Okay. I'm not actually sure I asked the question, but does this -- can you confirm that this appears to be a true and correct copy of your notes with respect to interviewing folks for your book Drug Dealer, M.D.?

A. Yes.

Q. Okay. Now, there's one -- they're not numbered so I want to ask you about --

MR. TSAI: Actually, can we go off the record.

THE VIDEOGRAPHER: Going off the record, the time is 3:24 p.m.

(Discussion off the record.)

THE VIDEOGRAPHER: Back on the record, the time is 3:25 p.m.

MR. TSAI: Thank you.

Q. So I've handed you -- we're looking at Exhibit 8, your notes in connection with your book. Could you please turn nine pages from the beginning, and I apologize. This doesn't have -- I mean your notes do not have internal pagination. So if you could flip nine full pages.

A. Nine pages from where we were?

Q. No, from the front. So let's count: One, two, three, four, five, six, seven, eight.

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A. Oh, you're not counting both sides?

Q. Eight. Eight flips, please.

A. Just one?

Q. Yes, that's one.

A. Okay.

Q. Since I'm not all that good at reading handwriting, I just did -- I did want to just confirm the accuracy of -- of the notes.

Do you see at top it says: "I could control it at first," and then right under that, it says "right after 9/11"?

A. I don't see that at the top. I wonder if I'm on the same page. Okay, yes, I do see that now.

Q. Great. And since you know your handwriting much better than I do --

A. Right.

Q. -- would you mind reading this particular interview, this particular page?

A. Sure.

"I could control it at first right. After 9/11, huge influx of cheap, super pure, chronic white heroin. $50 could last me two to three weeks. Am I becoming a heroin addict? I started reading William Burrough's book to see if it was me. The first time I went into heroin withdrawal, I didn't know it. I thought I just had the

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flu.

After two to three months of daily heroin use, I went back to California to get away from heroin and get my life together. I talked to my mom about it.

Back in New York City, I got buprenorphine as intramuscularly injected in a glass vial so I injected and I was doing Buprenex early 2001. It worked well the first time.

Moved back to New York. Six months, no heroin, but then I relapsed. Then I used needles to inject heroin using the Buprenex needles. Problems would happen when I would go out and have a drink or two, even after a party until 2:00 to 4:00 -- 2:00 to 4:00 in the morning, at 11:00 p.m. cocaine was useful.

I relapsed, alcohol to cocaine to heroin. Today use to maintenance therapy. Why not just stay on heroin? Tolerance going up and up to the point where I had an over a hundred dollar a day habit, trouble at school, nodding off.

Q. Okay. Thank you.

And just one point of clarification. On line 3, when you read "cheap, super pure," is the word after that China?

A. Yes.

Q. China, okay.

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So in your opinion, would this individual have opioid use disorder?
A. Yes, this individual had opioid use disorder.
Q. And taking this individual as an example, would you include this individual in what you've termed your dependence effect?
A. So this individual is actually a great example of the tsunami effect, which is to say that although she's in a minority group, having started her addiction with heroin, we know that's a minority group because more than 80 percent, according to Cicero, of heroin users today began with a prescription opioid.
She is somebody who then went from heroin to prescription opioids, which resulted in an exacerbation of her opioid use disorder, and I describe that several pages later, where she was admitted to the hospital for an abscess and a skin infection. And if you don't mind, I will read from my notes here to get a sense of what happened to her afterwards.
So she -- she was -- I think it's super relevant, super relevant to answering your question. So if you don't mind, I'd just like to read this short passage.
Q. Okay, sure. Which page is it?
A. This is just a couple pages after the page that

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you indicated.
Q. So two pages after what you just read into the record?
A. I think so. And you will see "IV fentanyl" at the top.
Q. That's three pages sequentially after what you just read into the record. Okay.
A. Okay. So actually, just before the IV fentanyl page, the prior page you'll see, in the second large paragraph, third sentence down, it says she was clean for six months. Then she had an infection at her injection site, MRSA -- which stands for Methicillan-resistant Staphylococcus aureus infection. Her arm was turning green and puffy, really scary. Then she relapsed to her dad's Dilaudid.
So, again, a great example of the tsunami effect, just the ubiquitous supply of prescription opioids in the community.
She was rushed to Stanford. Delirium, septic. Part of her arm rotted off. Didn't tell the doctors about the heroin.
Another great example of why it's so hard for front-line doctors to intervene, because they can't get the straight story from the patients themselves because there's so much stigma around this problem.

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She worried about how people would treat her. Doctors wouldn't work to save my life if they knew I wanted to get pain medication. Why is a healthy 24-year-old -- I can't read something -- dying.
Then she got IV Dilaudid to treat her pain and IV fentanyl. She had huge tolerance because she'd been using heroin. She had surgery every other day just trying to keep me alive.
3.5 five weeks in the ICU. At Stanford three months. IV Dilaudid every day. Full -- full anesthesia just to do the bandage changes every other day.
Flesh on calves and feet also rotted off. Sedated much of the time. Couldn't walk. Couldn't use on my own. IV vanco.
And then importantly, she spent almost three to six months at Stanford. Opioids were part of her daily regimen, and then she was given morphine tablets, 20 to 30 per month, and she was discharged with that high volume of pills, which she continued to get.
She dissolved them in salve and injected them in her pic line. So she was not given any addiction treatment. There wasn't awareness of her disease.
Then she got 5150 because the police came along and found her heating and injecting her extended-release morphine.

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And that was the first time they realized that I was basically suffering from an opioid use disorder.
But my -- my point in -- I think that's a really important piece to include in the story because what we have is this very complex relationship between illicit opioids, nonmedical use of prescription opioids, and legitimate use of prescription opioids. And all of those things interweave in really important ways that increase the risk of addiction overdose death for all Americans and would only have been possible because of the increased prescribing and increased supply, the nearly ubiquitous access, as a result in part of defendants' actions.
Q. And given this case history that we just discussed, would you include this individual within the scope of your gateway effect?
A. This individual wouldn't be included in gateway because she didn't begin with a prescription opioid, but she certainly would be included in the tsunami effect.
Q. As well as the dependence effect?
A. Yes. Because she -- the dependence effect is speaking more to those individuals who have developed a physiologic dependence to opioids, who don't meet clear criteria for an opioid use disorder. So she would really be in the tsunami effect.

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Q. Okay. Would you include this individual, given her case history and her development of addiction while she was in New York, within the scope of your -- of New York residents whose opioid addiction you would hold defendants responsible for?

MR. ARBITBLIT: Object to form.

THE WITNESS: So obviously when she was living in New York, that's when she started on heroin, not prescription opioids. But that doesn't release defendants from their responsibility regarding the opioid epidemic nationally, including in New York.

Q. BY MR. TSAI: So you would include this individual?

A. Yes, for the reasons that -- that I described having to do with how her opioid addiction was made worse because of the prescribing of prescription -- because of access to prevention opioids that followed her heroin use.

Q. And she wasn't prescribed that particular prescription opioid in her case; is that right? She got it from her dad. Am I reading that correctly?

A. No. So -- so there is an instance in which she got it from her father. That was the Dilaudid. But then she received high doses of opioids inhouse, and she was discharged with morphine sulfate, which she then

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injected.

Q. Okay. So I'm going to pivot and ask a short series of questions now are that specific to my client, Mallinckrodt, and then I'll pass to the other attorneys who haven't had a chance to ask questions.

So is your opinion in this case based on any FDA warning letter to Mallinckrodt?

A. I am not aware of any specific FDA warning letter to Mallinckrodt; however, I do know that other experts will be opining on the FDA.

Q. Okay. And one of the Mallinckrodt opioid medicines that you reference in your report is Xartemis.

Do you recall that?

A. Yes.

Q. And do you agree that by 2011, which was before Xartemis was even on the market, opioid prescriptions per person had begun decreasing in New York?

MR. ARBITBLIT: Object to form.

THE WITNESS: I think I do discuss this in my report. I'd like to reference my report.

Q. BY MR. TSAI: I think you're looking, perhaps, for page 17 through 18.

A. Thank you.

Q. Yeah.

A. Yes, I am.

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So as I state in my report: "In the state of New York, opioid prescribing increased from 101 morphine milligram equivalence in 1997 to 442 by 2006 and again increased to 492 per person in 2016," which would refute your claim that in New York opioid prescribing started to decrease around 2011.

It's also true that if you look at the duration of the prescription in New York, the length of opioid prescriptions actually increased between 2016 and 2017 from 15 to 19 days of opioids in 2017, an increase of 25 percent.

Q. Okay. Just let me try to understand.

In your report, you said based on a --

(Interruption in proceedings.)

Q. BY MR. TSAI: I read in your report based on IQVA data published by County by the CDC, the opioid prescribing rate in Nassau County increased from 46.0 to 51.1 prescriptions per hundred persons from 2006 to 2011. Thereafter, prescribing decreased similarly to the rest of New York state, with the rate per 100 persons of 36.0 in the most recent year of data available, 2017.

Do you see that?

A. Yes, I do.

Q. That's in your report?

A. Yes.

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Q. Okay.

A. Except that I want to say the reason for that apparent discrepancy -- it's not an actual discrepancy -- the CDC data are based on number of prescriptions written per 100 persons, whereas that particular New York State data is looking at how high the dose was and the length of the opioid prescription. So there are different ways to measure it.

So in terms of overall number of prescriptions written, those began to decrease around 2011, 2012, but the doses appeared to have gone up and the duration of prescriptions appear to have gone up.

Q. I see. Okay.

Is your opinion in that this case based on identifying any specific examples of individuals who allegedly became addicted to any opioid as a result of a prescription of a Mallinckrodt product in New York?

A. I don't have specific samples.

Q. Okay. And similarly, your opinion does not identify a single specific overdose death that, in your opinion, was allegedly the direct result of the ingestion of any opioid made by Mallinckrodt; correct?

A. Not at that level of specificity, no.

Q. Okay. Is your opinion in this case based on identifying any specific example of a particular opioid

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pill made by Mallinckrodt that was a suspicious order diverted improperly?
MR. ARBITBLIT: Object to form.
THE WITNESS: Not any specific pill.
Q. BY MR. TSAI: Okay. Is your opinion in this case based on identifying any specific example of a prescription of a Mallinckrodt opioid written in New York by a doctor or nurse relying on a representation from Mallinckrodt?
A. Not at that level of specificity.
MR. TSAI: Okay. All right.
Let me go off the record, and I will pass the witness at this time. Thank you.
THE WITNESS: You're welcome.
THE VIDEOGRAPHER: Going off the record, the time is 3:42 p.m.
(Discussion off the record.)
(Exhibit 9, JAN-MS-00362490, marked for identification.)
(Exhibit 10, Highlights of Prescribing Information, marked for identification.)
(Exhibit 11, JAN-MS-00362490, marked for identification.)
(Exhibit 12, Highlights of Prescribing Information, marked for identification.)

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THE VIDEOGRAPHER: Back on the record, the time is 3:48 p.m.
EXAMINATION
Q. BY MR. EHSAN: Good afternoon, Dr. Lembke. We met before at your prior deposition. My name is Houman Ehsan. I represent Johnson & Johnson and the Janssen defendants. Collectively, that they manufacture Duragesic transdermal fentanyl patch and Nucynta or tapentadol.
Doctor, you had talked about an efficient distribution system earlier today.
Do you recall that testimony?
A. Yes, I do.
Q. Do you consider the US Postal Service to be an efficient distribution system?
MR. ARBITBLIT: Object to form.
THE WITNESS: Well, it is a distribution system. I'm not sure how efficient it is.
Q. BY MR. EHSAN: Can it reach every small town in America, rain or shine?
A. I hope so.
Q. You mentioned several times that easy access and supply contributed to the overall opioid epidemic in the United States.
Do you recall that testimony?

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A. Yes, I do.
Q. And collectively, I think you referred to it at various times as the tsunami effect?
A. Yes.
Q. Considering access and the supply, did you consider illicitly manufactured opioids that entered the United States illegally?
A. I think that's part of the second and third waves of this epidemic. The increased supply began with prescription opioids, overprescribing, and then created a population of individuals who were addicted to those opioids, leading to increased demand, which then promoted the illicit market. Including heroin and illicit fentanyl.
So I think those things are tied in a sequential manner.
Q. Would you agree that that supply is not going to be disrupted by curbing opioid prescribing presently?
MR. ARBITBLIT: Object to form.
THE WITNESS: I disagree with that statement.
Q. BY MR. EHSAN: So it is your opinion that even if the FDA were to ban the prescribing of all opioids, that the supply side that is illicit in its manufacturing and distribution would somehow be lessened by that process?

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A. I have never endorsed, nor would I ever endorse that the FDA should ban prescribing opioids. What I have stated is that the opioids have been overprescribed and overdistributed and overdispensed, leading to a tsunami effect.
And I do believe that by engaging in safer and more judicious prescribing of prescription opioids, we will actually also, potentially in the long, long-term, be able to curb the opioid addiction problem more broadly, including addiction to illicit opioids.
Q. Do you lay out how the curbing of opioid prescribing and education, broadly speaking, will in the long term reduce the supply of illicitly manufactured opioids abroad?
A. The way that I lay that out in the report and in my testimony today is the way in which both nonmedical use and medical use of prescription opioids are interwoven and how both independently and together greatly increase the risk of an individual turning to a illicit source of an opioid.
So by managing the prescription opioid addiction oversupply, overdose problem, we will potentially treat the population of addicted persons we have iatrogenically created and then likewise decrease the demand for illicit opioids imported from elsewhere.

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Q. You understand that illicit opioids actually release non-opioid medications that are sold on the street as well?
MR. ARBITBLIT: Object to form.
THE WITNESS: Yes.
Q. BY MR. EHSAN: I can ask the question again. Was that a "yes"?
A. Yes.
Q. So someone who may have no exposure to opioids and may be addicted to cocaine may come into contact with illicitly manufactured opioids, fentanyl, specifically; correct?
A. Yes, and they also may come into contact with illicitly manufactured opioids.
Q. Have you looked at the size of the illicitly manufactured opioid market in the state of New York for your expert opinions today?
A. Did you say the illicitly manufactured opioid market?
Q. Yes, ma'am.
A. I have not specifically looked at that market in the state of New York.
Q. Do you know what the approximate market share of Duragesic is in New York?
A. No, I do not.

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Q. Do you know what the approximate market share of Nucynta is in the state of New York?
A. No, I do not.
Q. Do you have any historical knowledge of the market share going back in time?
A. No.
Q. Do you have a sense of how that market share compares to the size of the illicit market in the state of New York?
A. No.
Q. You mentioned that even short-term opioid prescriptions are not entirely benign.
Do you recall that?
A. Yes, I do.
Q. Can you identify for me any prescription that you've written for that is entirely benign?
MR. ARBITBLIT: Object to form.
THE WITNESS: No.
Q. BY MR. EHSAN: Would you agree with me that even water is not entirely benign?
MR. ARBITBLIT: Object to form.
THE WITNESS: I would agree that even water is not entirely benign.
Q. BY MR. EHSAN: As a psychiatrist, did you have occasion to ever treat someone with diabetes insipidus?

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A. Yes.
Q. And that is potentially a fatal condition from excess consumption of water; right?
A. Yes, it is.
Q. Did you, in your clinical practice, ever encounter patients who have had difficulty making co-payments for the medications that you had prescribed for them?
A. Yes, I have.
Q. And can that financial difficulty in paying the co-pay be an obstacle to the care of your patients?
A. Yes, it can.
Q. Now, you mentioned earlier today that you had reviewed some documents that suggested that McKesson had provided some free samples of Nucynta.
Do you recall that testimony?
A. Yes, I do.
Q. I want to hand you what's been marked as Exhibit 9 (indicating).
MR. ARBITBLIT: Do you have an extra copy?
MR. EHSAN: Yes.
Q. I ask you before we get to that to take a look at Exhibit 3.
A. Which one is Exhibit 3?
Q. Exhibit 3, yes, is your supplemental reliance

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list.
Do you see item number 13 there?
A. Yes.
Q. It is a -- it says JAN-MS-00864412; correct?
A. It does say that.
Q. And the document I've handed you which has been marked as Exhibit 9 bears that same Bates-stamp; correct?
A. That's correct.
Q. Is this one of the free samples that you were referring to regarding Nucynta?
A. Yes, it is.
Q. I'll draw your attention to a couple of points on this. Do you see that this document has a date of April 2010 at the bottom in the left-hand column midway through, it says Ortho McNeill Janssen Pharmaceuticals, Inc., 2009. Then next to that, it says April 2010.
Do you see that?
A. Yes, I do see that.
Q. And then is it your opinion, Doctor, that this provided the patient with free samples of Nucynta?
And if it helps, you can turn to the next page, where it says "patient instruction," and item 1 says: "Give your prescription for Nucynta along with this attached savings card to your pharmacist."
A. Right. So this is a coupon -- my understanding

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is that this is a coupon that allows the patient to be able to pay less for their Nucynta prescription.
Q. And do you think that's equivalent to a free sample?
A. Yeah, I think that could be equivalent to a free sample.
Q. And you understand that Nucynta is a Schedule II opioid?
A. Yes, I do.
Q. Are you aware whether or not Schedule II opioids can be given as free samples?
A. Well, this is a way to undercut the Schedule II regulations to make opioids more readily available. But more importantly, I cite this document as an example of the ways in which opioid distributors such as McKesson and opioid manufacturers such as Janssen have worked in collaboration to promote opioid prescribing, contributing to the oversupply problem.
Q. So if a doctor writes a prescription for Nucynta and a patient uses this coupon to reduce his or her co-pay, you see that as a nefarious thing?
A. In isolation, not necessarily. But in the broader picture of the conduct of defendants, yes, to me this is worrisome, especially when it seems to me that the various defendants are trying to say that the other

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one is to blame, when, in fact, they are working with one another.
MR. EHSAN: Move to strike that -- the rest of your response after the beginning as nonresponsive.
Q. Doctor, do you know what Nycynta's mechanism of action is?
A. Yes, I do.
Q. What is Nucynta's mechanism of action?
A. It's a norepinephrine reuptake inhibitor.
Q. And you understand if Nucynta is indicated for acute or chronic pain?
MR. ARBITBLIT: Object to the form.
THE WITNESS: Well, when you say is indicated for acute or chronic pain, what are you basing that on?
Q. BY MR. EHSAN: You understand drugs come with indications?
A. Yes, I do.
Q. Do you know that this particular Nucynta coupon, is it for a Nucynta that's indicated for chronic pain?
MR. ARBITBLIT: Object to form.
THE WITNESS: I'd like to see the source that Janssen relied upon to promote Nucynta for chronic pain. It was based on what?
Q. BY MR. EHSAN: Again, I don't think you understood my question so let me try it this way.

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I'm going to hand you what's been marked as Exhibit 10 (indicating). I will show you that.
So this is the -- I'll represent to you this is the very first label, which is the approval for tapentadol under the tradename Nucynta. In fact, this one doesn't even have the tradename in the label yet, but it is tapentadol.
And you'll see the initial US approval was 2008, and that this particular document was revised in November of 2008.
Do you see that?
A. Where does it say it was revised? Oh, down below.
Q. Yes.
A. I see that.
Q. If you look at the indications of use, again, the trade name is missing in this early label, but is an opioid analgesic indicated for the relief of moderate to severe acute pain in patients 18 years or older.
Do you see that?
A. I do see that.
Q. Okay. So would this indicate at least that there is a version of Nucynta that only has an acute pain indication?
A. This would assert that this version of Nucynta

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has an acute pain indication.
Q. And do you see where the dosage forms and strengths of the tablets are available in 50, 75 and 100 milligrams?
A. I do see that, yes.
Q. Okay. You can put that aside. I'm going to show you one more document here (indicating). This is Exhibit 11.
And do you see that this is another coupon where -- that the top states up to ten free pills of Nucynta, 50, 75 or 100 milligram.
Do you see that?
A. I do see that.
Q. And it says, again to the patient, that present your written prescription for Nucynta.
Do you see that?
A. Present your written prescription for up to ten Nucynta.
Q. 50, 75 or 100 milligram tablets; correct?
A. Yes.
Q. These dosages would be consistent --
A. I would just -- I would just add for completeness, this voucher to your pharmacist, give this voucher to your pharmacist to receive your free trial.
Q. Again, but it requires a prescription for

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Nucynta; correct?
A. (Nods head.)
Q. And presumably that doctor has made a decision that Nucynta is an appropriate medication for acute treatment of pain in that patient; correct?
MR. ARBITBLIT: Object to form.
Q. BY MR. EHSAN: Is that a "yes"?
A. Yes.
Q. And that this allows the patient to offset the cost of the medication; correct?
A. It allows for a free trial.
Q. Would that mean that -- so assume this coupon didn't exist. Would you then advocate that the patient not take the medication because he or she can't afford it?
MR. ARBITBLIT: Object to form.
THE WITNESS: I'd really have to know the details of the specific case in order to weigh in on that question.
Q. BY MR. EHSAN: So you can't say that it would be better for the patient to get the medication he or she was prescribed or not be able to afford it? That requires more information to make that distinction?
MR. ARBITBLIT: Object to form.
THE WITNESS: Yes. Because given the prevailing

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pattern of opioid prescribing in the last ten years, I can't be certain that this patient should actually be prescribed an opioid analgesic, even for acute pain.
Q. BY MR. EHSAN: Do you agree that there are randomized clinical trials showing efficacy of opioids for the treatment of acute pain?
A. I do. But it doesn't mean that opioids are without risk, even in an acute setting. It's all about the risk-benefit calculation.
Q. Understood. We, I think, established that there's a risk associated with every prescription.
I'm going to hand you what's been marked as Exhibit 12 (indicating).
And Doctor, I'll represent to you this is the first or approval prescription -- or sorry -- labeling for Nucynta ER, which is the long-acting version of Nucynta, and it was actually approved in 2011, and that by dating purposes, it postdates the April 2010 coupon; correct?
This would be Exhibit 9.
A. April 2010 and 2011, yes, it appears to postdate that.
Q. And likewise, if you look at the dosage forms and strengths, it's not available in a 75-milligram version, is it?

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A. Where are the dosages forms and strengths?
Q. So sure. Left-hand column, next-to-last segment.
A. 50, 100, 150, 200, 250. No, it's not available in 75.
Q. So likewise, what I handed you in Exhibit 11 would be inconsistent with a reference to the long-acting version of Nucynta; correct?
A. Not necessarily because it is available in 50 and 100.
Q. So you're suggesting the coupon is referring to two different Nycyntas in the same construct? If that's your understanding, that's fine. I'm not going to take time to debate that issue, but is that your opinion?
A. Well, it's not -- it's not clear to me which Nucynta the coupon is referring to.
Q. Okay. Now, Doctor, if you don't mind looking at again the very first page of Exhibit 12, do you see there is an indication and usage section?
A. Yes, I do.
Q. Would you mind reading that, please.
A. "Nucynta ER is an opioid analgesic indicated for the management of moderate to severe chronic pain in adults whom continuous around-the-clock opioid analgesic is needed for an extended period of time."

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Q. Would you agree with me, Doctor, that that indication is for the use of Nucynta in the management of chronic pain?
MR. ARBITBLIT: Object to form.
THE WITNESS: Yes.
Q. BY MR. EHSAN: Now, do you agree with this indication for Nucynta?
A. I think this indication is not supported by the evidence. I do reference some of the efficacy studies in my report. Afilalo, et al., compared Nucynta to placebo and I believe oxycodone and found no clinically meaningful difference in a 12-week study.
And as far as I know, there are no studies that are placebo-controlled randomized trials longer than 12 weeks using Nucynta, tapentadol, in the treatment of chronic pain.
So I feel that this indication is not informed by the evidence.
Q. I'll just -- two quick questions, and I realize I'm trying to make things quick here, given the timing.
But the Afilalo study references or comparing Nucynta to oxycodone, another active opioid; right?
A. Yes, and to placebo.
Q. Could you turn to page 12 of Exhibit 3 that I handed you. That's the label for the long-acting

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Nucynta. You have it, I think.
A. I have it? Okay, yes.
Q. If you turn to page 3 of that document. You have it.
Do you see that there is a series of warnings surrounded by a box?
A. Yes, I do.
Q. Are you familiar with the term "box warning" or "black box warning"?
A. Yes, I am.
Q. Do you see in the middle of that black box warning related to Nucynta ER, there's a section titled "Proper Patient Selection"?
A. Uh-huh.
Q. Could you please read that.
A. "Nucynta is an extended-release formulation of tapentadol indicated for the management of moderate to severe chronic pain in adults when a continuous around-the-clock opioid analgesic is needed for an extended period of time."
Q. Do you feel -- you believe that is a false or misleading statement?
A. I feel that this statement is not informed by reliable evidence because it takes a study that provides weak evidence for efficacy in acute pain and presumably

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extends that to the treatment of chronic pain.
Q. Do you have an understanding of what studies the FDA reviewed in its approval and ultimate decision for the indication of Nucynta ER?
A. I believe that they did base their approval on the Afilalo study and I think also the Buynak study in 2010.
Q. And you think the totality of the evidence that the FDA reviewed in connection with the indication for Nucynta ER does not support the indication the FDA ultimately granted Janssen for the drug; is that correct?
A. Yes, I would say that's true.
Q. Would you think that the FDA was just wrong on this issue?
A. I think the FDA was wrong on this issue, yes. But there are other experts who will be opining on the FDA and on FDA labeling.
Q. Focusing your attention on the indication for Nucynta ER, it talks about management of moderate to severe chronic pain when a continuous around-the-clock opioid is needed.
Do you see that?
A. This is under "proper patient selection" again?
Q. No. If you go back to page 1. I apologize for not being very clear. Under the "indication" section.

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A. Yes.
Q. Now, how would a physician know that a patient required around-the-clock or continuous opioid analgesic?
MR. ARBITBLIT: Object to form.
THE WITNESS: I guess could you be more specific in your question? It seems that the question could encompass many different clinical scenarios.
Q. BY MR. EHSAN: Sure. Let me just tell you -- put it differently.
Would it be fair to say that in order for someone to require around-the-clock opioid analgesic, he would qualify for the indication under Nucynta, that he or she would have to be on some amount of opioids before getting to the Nucynta prescription?
A. Are you asking me about my opinion regarding the use of opioids in the treatment of chronic pain or are you asking me about the common practice?
Q. Dr. Lembke, you said you had 20 years of practice or medical practice experience and you relied on your other clinical judgement, and I'm just taking it from a perspective of a physician who's prescribed opioids as well, that you don't start someone with a dose of a long-acting, continuous opioid unless you know how much opioids they could tolerate, i.e., they should probably be on some level of regular short-acting opioids

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and you're transitioning them to a long-acting opioid.
MR. ARBITBLIT: Object to form.
THE WITNESS: So I'm not sure that the actual practice as it occurs in the United States necessarily follows what you just said. I think that patients are started on long-acting opioids by some physicians even when they've not been on short-acting opioids, so...
Q. BY MR. EHSAN: Understood. And I'm sorry, it was suggested that the United States meaning that I don't have experience with the practice in the United States or are you just saying that you have a different sense of where I've come from in terms of my clinical experience versus yours? I'm just curious about that.
A. I know nothing about your clinical experience.
Q. But you believe in the United States it is not standard practice to take a patient first on a short-acting opioid, then transition them to a long-acting opioid?
A. I think that practice varies greatly and that we are in a situation where many doctors without pain expertise, in particular front-line primary care doctors, have been put in the position of prescribing opioids without really being given proper training on how to do that, and so I think practice patterns vary greatly.
Q. Do you know anything about the specific practice

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patterns in New York?
A. I've commented previously on New York and what I have looked at and what I haven't looked at.
Q. Two -- two more quick questions.
Doctor, you said you worked with a DEA agent in Oakland recently.
Do you recall that?
A. Correct.
Q. Would you be willing to provide that agent's name?
A. I'd be happy to do that.
Q. Okay. Can you provide that?
A. I'd have to look at my records. I --
MR. EHSAN: Fair point.
And I'd just ask your counsel that if Dr. Lembke could provide that name, that you could provide it to us.
MR. ARBITBLIT: If the agent himself or herself has no reason to object, then I would have no reason to object. And I don't know whether the witness has the right to speak for that person.
If she's willing and the agent that she spoke to is willing, then I'm willing.
MR. EHSAN: Well, I asked her a question. She said she was willing.
MR. ARBITBLIT: And you asked me a question and

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I gave you an answer. She may not have the authority to speak for that person.
MR. EHSAN: Under what --
MR. ARBITBLIT: I don't know. I'm not saying that I won't provide it. You're just making an argument that doesn't necessarily have a basis. We may be in complete agreement.
Q. BY MR. EHSAN: Then, Dr. Lembke, are you aware of any marketing by Janssen that led to any inappropriate prescription for Duragesic or Nucynta in the state of New York?
A. So I'm aware of marketing efforts by Janssen and lobbying efforts and funding efforts by Janssen on a national level that did affect prescribing patterns across all the states, including the state of New York.
Q. Let me be a little more specific.
Can you identify a single prescription in the state of New York for either Duragesic or Nucynta that was -- let's just take it sequentially -- that was, one, improper?
A. I'm not --
MR. ARBITBLIT: Object to form.
THE WITNESS: At that level of specificity, no, not a single prescription.
Q. BY MR. EHSAN: Two, based on a misrepresentation

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by Janssen or any of its affiliates to the prescribing doctor?
MR. ARBITBLIT: Object to form.
THE WITNESS: I believe that Janssen and Janssen affiliates' misrepresentation have impacted prescribers in New York.
Q. BY MR. EHSAN: But can you identify a single doctor that was misled by Janssen?
A. Yes, I can identify doctors that I have spoken to in New York who said that they were misled by the misrepresentations by the opioid pharmaceutical industry, including Janssen, but not specifically referring to Janssen.
Q. So none of them specifically mentioned Janssen?
A. No.
MR. EHSAN: Thank you, Doctor. I will pass the witness.
THE VIDEOGRAPHER: Going off the record, the time is 4:17 p.m.
(Recess.)
THE VIDEOGRAPHER: Back on the record, 4:25 p.m.
EXAMINATION
Q. BY MS. VICARI: Dr. Lembke, my name is Angela Vicari, and I represent the ENDO and Par defendants in this case.

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Do you know what opioid medication -- medications ENDO manufactures?
A. Yes. ENDO manufactures OPANA ER, Percodin, Percocet, and generic forms of oxycodone, oxymorphone, hydromorphone and hydrocodone.
Q. Do you know what opioid medications Par manufactures?
A. I'm not familiar with the ways in which ENDO and Par relate to each other, but it could be that some of those are, in fact, manufactured by Par or were manufactured by Par before being acquired by ENDO. I'm not familiar with the acquisitions process.
Q. And I noticed in answering that question, you're referring to a document. Is that document part of your report?
A. This document is part of the Complaint.
MS. VICARI: Can we mark that. I'd like to mark that as an exhibit in the deposition.
I'd like to mark that document as Exhibit Number 13. Oh, it's already marked as 5?
MR. ARBITBLIT: It's part of the exhibit that counsel asked earlier that we reproduce for you. So it's part of Exhibit 5.
MS. VICARI: Okay. Thank you.
Q. Now, Dr. Lembke, is it your understanding that

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other experts are offering opinions regarding the adequacy of ENDO's suspicious order monitoring systems?
A. Yes.
Q. And you're not offering any opinions regarding the adequacy of ENDO's suspicious order monitoring systems; correct?
A. I'm not offering specific opinions on ENDO, but as stated in my report, I do offer an opinion on the role of distributors, manufacturers and pharmacies in creating the oversupply that led to the opioid epidemic.
Q. Do you know anything about the way in which ENDO monitored suspicious orders?
A. I know that in general, opioid manufacturers look at reports of -- actually, I would -- I would defer that to other experts.
Q. So you're not offering any opinions regarding the adequacy of ENDO's suspicious order monitoring system; correct?
A. That's correct.
Q. And you're not offering any opinions regarding the adequacy of Par's suspicious order monitoring systems; correct?
A. That's correct.
Q. And you said earlier other experts will be opining on FDA issues; is that correct?

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A. I do mention the FDA in my report in several places. If you'd like, I can go to those sections.
Q. My -- that's okay.
You're not offering any opinions regarding ENDO's compliance with FDA regulations; correct?
A. That's correct.
Q. And you're not offering any opinions regarding Par's compliance with FDA regulations; correct?
A. That is correct.
Q. Now, Dr. Lembke, all the documents that you considered in forming your opinions are set forth in Exhibit B to your report and the supplement that was provided last night; correct?
A. That is correct, but I would add to that I was the recipient of ENDO and other defendants' marketing material throughout my medical career. Those are not -- those are not listed, but those are part of what has contributed to my opinion.
Q. And what documents that are not listed in Exhibit B or the supplement did you receive from ENDO during the course of your medical career?
A. I can't speak to ENDO specifically, but in terms of opioid manufacturers and their influence on pain as the fifth vital sign on the Federation of State Medical Boards on pain guidelines, I was the recipient of those

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marketing efforts.
Q. And a lot of those materials are in your report. I was asking which materials that are not in Exhibit B or the supplement to your report did you receive from ENDO?
MR. ARBITBLIT: Object to form.
THE WITNESS: As answered, the materials that are cited in my report as well as my clinical experience and my experience as a clinician being influenced by the marketing material in real time as it unfolded in the '90s and early aughts through today have contributed to my opinion.
So I wouldn't want you to be under the mistaken conclusion that it's just those listed documents gathered for the purpose of writing the report.
Q. BY MS. VICARI: Do you intend to offer opinions at trial regarding ENDO -- any ENDO documents that are not included in Exhibit B or the supplement to your report?
A. If there's a document that you'd like me to see in addition, I would be happy to review it.
Q. There's no document that I wish to show you.
Sitting here today, do you intend to offer any opinions at trial concerning any ENDO documents that are not included in Exhibit B or the supplement to your report?

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A. Not unless I'm asked to review an additional document, which I would be happy to do.
Q. And in forming your opinions as to ENDO in this case, you did not consider any deposition testimony given by ENDO witnesses; is that correct?
A. That is correct.
Q. And in forming your opinions in this case, you did not consider any deposition testimony given by any Par witnesses; is that correct?
A. That is correct.
Q. And it's fair to say that in forming your opinions, you didn't review all of ENDO's opioid marketing materials; correct?
A. That is correct.
Q. To the extent that you considered ENDO documents in forming your opinions, you've reviewed those documents thoroughly; correct?
A. Yes.
Q. And to the extent that as a result of your review of an ENDO document, did you include all of the statements that you believe to be misleading in your report?
A. I included representative samples. I didn't include all of the misleading documents. There were so many that it would have been a very long report to

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include all of them, but I included representative examples.
Q. Which ENDO documents -- in your opinion, which ENDO documents contained misleading statements that were not included in Exhibit B to your report or the supplement?
MR. ARBITBLIT: Object to form.
THE WITNESS: I don't remember now, but when I found a statement that was repetitive of other misrepresentations, I just tried to use several examples, not every single example, because it would have been redundant.
Q. BY MS. VICARI: Dr. Lembke, you have not conducted any analyses to determine which, if any, prescriptions of ENDO opioid medications in New York state were medically inappropriate, have you?
MR. ARBITBLIT: Object to form.
THE WITNESS: As stated before along similar lines of questioning, I have not analyzed documents at the level of individual documents produced by ENDO in the state of New York. But I would qualify that by saying I believe that prescribers in the state of New York were exposed to the same misleading marketing messages as doctors all across the country.
Q. BY MS. VICARI: And same question as to Suffolk

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County. Is your answer the same?
A. Same answer.
Q. And same question as to Nassau County. Is your answer the same?
A. Same answer.
Q. You have not conducted any analysis to determine when -- whether any particular prescription of an ENDO medication in New York state was influenced by ENDO's marketing; correct?
MR. ARBITBLIT: Object to form.
THE WITNESS: I would refer to my answer to the last question, which I think is essentially the same answer.
Q. BY MS. VICARI: And same question as to Suffolk. Is your answer -- is your answer the same?
A. Yes, it is.
Q. Okay. And the same question as to Nassau County. Is your answer the same?
A. Yes, it is.
Q. Dr. Lembke, would you agree with me that any ENDO document that was an internal-only document, not seen by physicians, could not have been relied on by doctors in New York state in their prescription of an opioid to a patient?
A. Well, I think internal documents not seen by a

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prescribing physicians are a window into the campaign that ENDO and other defendants were launching to convince prescribers.
I think there were many instances of misrepresentation for which there's documentation at all, and of course, those can't be included.
Q. I guess my -- my question was not as to messaging; it was to the particular document.
Is it your -- you would agree with me that any ENDO document that was internal only and never seen by a physician, that document could not have been relied on by a physician in making a prescribing decision; correct?
MR. ARBITBLIT: Object to form.
THE WITNESS: Well, I disagree with that because an internal ENDO document could easily have influenced the external communications with prescribers and hence influence their prescribing.
Q. BY MS. VICARI: Dr. Lembke, can you identify for me any individuals who died as a result of taking an opioid manufactured by either ENDO or Par in either the state of New York, Suffolk County or Nassau County?
A. No.
Q. And Dr. Lembke, can you identify for me any individuals who overdosed on an opioid manufactured by ENDO or Par in New York state, Suffolk County or Nassau

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County?
A. Not at the level of an individual by name. Not at that level.
Q. Okay. And if I asked the same question with respect to abuse of an ENDO or Par opioid, is your answer the same?
A. Yes.
Q. Okay. And you can't identify for me anyone who misused an ENDO or Par opioid in the state of New York, Suffolk County or Nassau County, can you?
A. Not by name, no.
Q. And similarly, you can't identify any individual who became addicted to an ENDO or Par opioid in the state of New York, Suffolk County or Nassau County; correct?
A. Correct.
Q. Now, Dr. Lembke, when you encounter a patient who you learn has abused a prescription opioid, do you report that abuse as an adverse event to the manufacturer of that opioid?
A. I have not done that, no.
Q. And when you encounter a patient who you know misused a prescription opioid, do you report that as an adverse event to the manufacturer of the opioid?
A. I've not taken that action, but I have written and spoken widely on the problem of prescription opioid

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misuse and addictive use as a way to try to raise awareness. So I have taken other measures to raise awareness.

Q. But you haven't submitted an adverse event report to the manufacturer in that case; correct?

A. No, I haven't, and that is largely because my awareness of the opioid problem really began after I graduated from medical school and finished my residency training, and at that point, I was not prescribing opioids until I began to prescribe buprenorphine for the treatment of opioid use disorder.

Q. Well, when patients come to you for the treatment of opioid use disorder today, you testified earlier some of them are abusing prescription opioids; correct?

A. Yes, that is true.

Q. And do they tell you which opioid they are abusing?

A. Sometimes they do, yes.

Q. And when they tell you which opioid and they are, I'll say, misusing, do you report that as an adverse event to the manufacturer of that opioid?

A. That has not been my practice.

Q. And when you encounter a patient who you know has become addicted to a prescription opioid, do you

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report that case of addiction to the manufacturer of the opioid as an adverse event report?

A. I don't report it as an adverse event report to the manufacturer, but I certainly do alert the other healthcare providers taking care of that patient. I alert in some instances the pharmacist who's dispensing for that patient.

Q. And do you report any known diversion of a prescription opioid to the manufacturer as an adverse event?

A. As stated before, it's very hard for me to be aware of diversion in real time because patients will not admit to it. It's only in the past tense that they'll admit to it. I've had instances of being suspicious of diversion, but not enough to, let's say, involve criminal justice or report it at that level.

Q. Now, Dr. Lembke, it's your position and your opinion in this case that there's no reliable scientific evidence showing that the long -- that long-term opioid therapy is effective for chronic non-cancer pain; is that correct?

A. Yes, that's correct.

Q. And by "reliable scientific evidence," you mean a randomized placebo-controlled trial in excess of three months; is that correct?

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A. Yes.

Q. How would you design a randomized placebo-controlled trial to determine whether opioid therapy is effective for chronic non-cancer pain?

A. Well, I would try to use a real clinic population, not a rarified sample. So I would try to base it in a clinic and recruit patients who were representative of the types of patients we see in real clinical care.

I would try, as the SPACE trial did, to assess their impressions of opioids prior to initiating therapy.

I would randomize those individuals to comparable groups, one group to receive opioids and another to receive placebo in a blinded -- double-blinded fashion, so neither the providers -- prescribers or patients themselves knew which they were getting.

Q. Uh-huh.

A. And then I would try to use comprehensive measures that are clinically meaningful to assess their subjective pain relief but also their objective function and many other potential adverse health consequences, including the risk of misuse and addictive use. That's just a start.

Q. You mentioned the SPACE trial. Do you believe that there was any selection bias in the SPACE trial?

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A. So the SPACE trial itself said that there was some bias in favor of opioids a priori.

Q. Is that the only bias that you're aware of in the SPACE trial?

A. Well, the SPACE trial used an opioid-naive sample. That's not a bias, but there are lots of patients who are already on opioids that should also be counted.

And, of course, you know, 12 months, although a long time compared to most studies, is still probably not sufficient to assess the true risk of opioid addiction. When patients are receiving prescription for an opioid in clinical care, there are data showing that median length of time to developing an opioid addiction is approximately three years.

MS. VICARI: Thank you, Dr. Lembke, for your time. I'll pass the witness.

Can we go off the record while we pass the witness.

MR. ARBITBLIT: Yes, thanks for asking.

THE VIDEOGRAPHER: Going off the record, the time is 4:42 p.m.

(Discussion off the record.)

(Exhibit 13, ALLERGAN_MDL_01361692 - 1850, marked for identification.)

(Exhibit 14, WIS_PPSG_003892, marked for identification.)

THE VIDEOGRAPHER: Back on the record, the time is 4:45 p.m.

EXAMINATION

Q. BY MS. RIVERA: Good afternoon, Dr. Lembke.

A. Good afternoon.

Q. My name is Maria Rivera. I'm from the law firm of Kirkland & Ellis, and I represent Allergan Finance, LLC, in this case.

If you wouldn't mind in Exhibit 2, which is your report, turning to Appendix B, which is your relied upon list.

And if you would turn to page 49 of that relied upon list, please.

A. 49 of the relied upon list. Yes, I'm there.

Q. Yes, ma'am.

Am I correct that this is where you list the document -- or the defendant-specific documents that you reviewed and relied upon in reaching your opinions in this case?

A. Yes, this is the documents that I relied upon.

Q. Okay. And am I correct that there are six Allergan-produced documents on that list?

A. Yes.

Q. Okay. So is it fair to say that those are the only Allergan-specific documents that you reviewed to reach any Allergan-specific opinions in your report?

A. No, because I was the recipient of multiple Allergan promotional material throughout my medical career. So that is also part of what forms the basis of my opinion.

Q. Okay. Can you identify any specific Allergan promotional material that you received during your career that you're relying upon for purposes of your opinions in this case?

A. I do have some memories of Allergan promotional material for Actiq or fentanyl lollipops through my medical training because I remember being so shocked that fentanyl would be put in lollypop form.

Q. And is it your understanding that those are Allergan products?

A. Oh, sorry. Those are Teva products. You're right. Sorry.

Q. Okay. So let me ask my question again.

Do you have or can you identify any other Allergan-specific documents or materials that you're relying upon for your opinions in this case with respect to Allergan, other than the six documents that are listed in Appendix B to your report?

A. No.

Q. Now you, as was mentioned, did serve a report in the MDL case as well.

Do you recall that?

A. Yes.

Q. Okay. And I'll represent to you that in that case, you listed only five Allergan Bates-labeled documents. And the document that you added is number 667 in your New York report, and I'm going to hand that to you, which has been marked Exhibit 13 (indicating.)

MR. ARBITBLIT: Thank you, Counsel.

Q. BY MS. RIVERA: And let me just back up and ask you one question.

Were the six Allergan-produced documents that you reviewed provided to you by your counsel?

A. Yes, they were.

Q. Okay. And do you have an understanding that Allergan has produced hundreds of thousands of documents in this case; correct?

A. That is correct.

Q. But you didn't think it was necessary to review any more Allergan documents that the six that are listed in your report; is that correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: I lived through this promotional

campaign, and the Allergan documents that I reviewed were consistent with my lived experience of pharmaceuticals' promotional messages. So because those themes were saturated, no, I didn't think it was necessary. But if there are any documents that you would like me to review, I would be happy to review them.

Q. BY MS. RIVERA: Okay. But the answer to my question about whether you didn't think it was necessary to review any more Allergan documents that the ones that are listed in Appendix B is "yes"; correct?

MR. ARBITBLIT: Object to form, asked and answered.

THE WITNESS: I did answer that question.

Q. BY MS. RIVERA: Okay. The document that I handed you, which is Exhibit 13, is the one that you added to your report.

In looking at this document, which is entitled "ER/LA Opioid REMS," do you see that this document was created by The Collaboration For REMS Education?

A. Yes, I do.

Q. Okay. So in looking at this document, would you agree with me that is not a document that Allergan created?

A. I can't be sure of that. I'm not sure what The Collaborative For REMS Education consists.

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Q. Are you able to tell whether any statements in this presentation are attributable to Allergan?
A. This presentation, as I'm recalling it, is a more general presentation on opioids, and I don't believe it lists any specific opioid products, although I may be wrong about that.
Q. Okay. From looking at this presentation, though, you can't say that any of the statements in here are attributable to Allergan; correct?
A. Well, what I would say is that the promotional efforts of Allergan more broadly have contributed to the kinds of statements that are in these educational materials that have contributed to a prescribing pattern which is not consistent with the evidence.
Q. Okay. I understand, Dr. Lembke.
My question was: This document doesn't have any indication if the statements in it were made by Allergan or not?
A. Well, again, what I'm trying to -- to say is to draw a distinction between specific products and the paradigm shift or the cultural change in medicine around opioid prescribing, which I do believe Allergan and other defendants had a hand in.
Q. I understand, but that wasn't my question.
My question is: You can't tell from this

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presentation whether any of the statements in it were made by Allergan or written by Allergan?
A. Well, many of the references on many of these slides involve organizations that received funding from opioid Pharma so that it is possible that some of these slides were influenced by Allergan. So I wouldn't want to say for sure.
Q. It's possible, but you don't know if that's the case; correct?
A. Well, I wouldn't want to say that Allergan didn't influence the content. I believe that Allergan and other opioid manufacturers did greatly influence the content of these kinds of learning materials.
Q. Okay. Can I ask you how -- why you added this to your relied upon list from your MDL report to your New York report?
I can represent to you that it's not cited anywhere in the body of your report or in your appendix with respect to Allergan.
A. Okay.
Q. In fact, let me withdraw my question and ask you a different one.
A. Okay.
Q. If this presentation is not listed anywhere in your report or in your appendix that's specific to

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Allergan, can I assume that you didn't rely upon this presentation in reaching your Allergan-specific opinions?
A. No, that's not correct.
Q. Okay. But you can't tell me, sitting here today, how you relied upon this with respect to Allergan?
A. So I relied upon this as an example of educational materials disseminated to healthcare providers that misrepresents the evidence around opioid prescribing, and I detail in many places in my report how opioid manufacturers, distributors and pharmacies contributed to this misrepresentation of the evidence and the oversupply that's the essence of my report.
Q. Okay. Let's move on.
You testified earlier, I believe, that you did not conduct any type of regression analysis. I'll try to get the language right.
You did not conduct any type of regression analysis to isolate the impact that any opioid -- opioid marketing by any individual defendant had on New York prescribers; is that correct?
A. That is correct.
Q. Okay. Am I correct that you didn't do any type of analysis, regression or otherwise, to isolate the impact that any opioid marketing by any individual defendant had on the prescription levels of opioids in

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New York?
A. So I read the analyses of others on specific New York prescribing, and those are in my report, and I've cited those in testimony. But I did not do my own individual crunching of numbers, as it were.
Q. Okay.
A. I have done lots of qualitative analyses that I do think apply to the State of New York and Suffolk and Nassau counties.
Q. Understood. And that would mean that you haven't done any independent analysis to try to determine the impact of Allergan-specific promotional activity on the levels of prescribing in Northern California or in Suffolk County or in Nassau; correct?
A. Incorrect. I believe that I have done my own independent analyses, as evidenced by peer-reviewed articles I've written, as evidenced by my book, that very carefully details the role of opioid manufacturers -- Allergan is one example -- in creating the overprescribing and oversupply of opioids leading to the opioid epidemic.
That is an analysis that I did, a causal analysis.
Q. Okay. Have you done -- am I correct that you have not done any quantitative analysis in order to

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quantify how, if at all, Allergan's promotion contributed to the level of opioid prescribing in New York?
A. I would respectfully disagree with that. I've published a paper on which prescribers are prescribing the most opioids, using a national database, Medicare database, including prescribers in the state of New York. And that is a quantitative analysis.
Q. Have you done any -- do you have an opinion and are you offering an opinion about the quantitative impact that Allergan's opioid marketing had on prescription levels in New York?
A. I'm not quantifying Allergan's role, but I am offering an opinion that Allergan contributed to increased prescribing in the state of New York.
Q. Okay. But you haven't done any analysis to quantify what that impact was?
A. Well, I have done a quantitative analysis in the article that I published in JAMA looking at who is prescribing opioids, and what we saw was no geographic variation in that pattern across 50 states.
And I've also, as I said, done a qualitative analysis which I believe represents the same problems in New York as everywhere else in the country.
Q. Am I correct, Doctor, that you don't know how many details Allergan sales reps conducted in New York?

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A. That is correct.
Q. And you don't know how the number of Allergan details compares to any other defendants?
A. That is correct.
Q. And you don't know how many prescriptions of Allergan's opioid products there were in New York?
A. That is correct.
Q. And you don't know what Allergan's market share of opioid prescriptions was in New York; is that right?
A. That is correct.
Q. And am I correct that you cannot name any individual doctor in New York that wrote a prescription for an Allergan opioid that they would not have otherwise written because of Allergan's promotional marketing?
MR. ARBITBLIT: Object to form.
THE WITNESS: Again, my prior answer regarding the overall influence of the opioid industry on overprescribing of opioids does apply to New York as well.
Q. BY MS. RIVERA: But you cannot identify a specific doctor in New York that wrote a prescription as a result of Allergan's promotional activity; correct?
A. I have spoken to doctors who practice in New York who communicated to me that they were influenced by the misleading of the opioid pharmaceutical industry, but

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not at the level of specificity of naming specific opioid manufacturers.
Q. Can you identify a specific individual who died or overdosed in New York as a result of taking an Allergan opioid?
A. Same -- same answer as the last question.
Q. Can you answer it for me more specifically to this question? Can you identify a specific individual who died or overdosed in New York, Suffolk County or Nassau County, as a result of taking an Allergan opioid?
MR. ARBITBLIT: Object to form.
THE WITNESS: Not by name.
Q. BY MS. RIVERA: Can you identify any individual in New York who became addicted to any opioid or misused any opioid as a result of taking an Allergan opioid product in New York?
A. Not by name.
Q. Can you identify any individual description in New York, Suffolk County or Nassau County, of an Allergan opioid that was medically inappropriate?
A. Not by name.
Q. Just a few more questions.
Based on your experience, Doctor, would you agree that sometimes manufacturers will detail physicians for the specific purpose of trying to promote

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substitution of one opioid for another opioid?
MR. ARBITBLIT: Object to form.
THE WITNESS: Can you rephrase your question?
Q. BY MS. RIVERA: Sure.
In other words, are you familiar that -- with the fact that manufacturers may detail physicians in order to try to convince them to switch from one opioid to another opioid?
A. Yes.
Q. Okay. And if that detailing is successful and the doctor switches from one opioid to another opioid, that is not increase in the overall level of opioid prescriptions, is it?
MR. ARBITBLIT: Object to form.
THE WITNESS: It really depends on whether or not that switch, which is most commonly done to try to overcome tolerance, actually leads to an increase in the total of morphine milligram equivalence of that opioid, which is one way to measure increase in supply.
Q. BY MS. RIVERA: Okay. And if it doesn't lead to an increase in the total morphine milligrams and it's just switching the same level of milligrams from one opioid to another, that does not increase the overall level of opioid prescriptions, does it?
MR. ARBITBLIT: Object to form.

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THE WITNESS: Well, it might do if it leads to more prolonged exposure to that opioid as a result of the switch. So not only had the last three decades been characterized by increasing doses of opioids, but also increasing duration. More than 80 percent of individuals receiving opioid therapy are on long-term opioid therapy despite the absence of evidence for long-term use.

Q. BY MS. RIVERA: Okay. Let me hand you what's been marked as Exhibit 14 very quickly (indicating).

MR. ARBITBLIT: Copy, please.

MS. RIVERA: Oh, sorry.

Q. In your Appendix 2, you identify some documents that you believe support that manufacturers supported the Wisconsin Pain and Policy Study Group?

A. Yes.

Q. Okay. And I'll represent to you that the document that you cited with respect to Allergan and Actavis is the document that I just handed you as Exhibit 14.

And you can see that -- sorry, on page 5 of your Appendix 2, paragraph 22 also page 5 of the Pain and Policy Study Group appendix?

A. Yep.

Q. Paragraph 22?

A. Yep.

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Q. Okay. And so this is the document that you cited to support that Allergan or Actavis had supported that Pain and Policy Group. I'll represent to you that there is no mention of Allergan or Actavis in this document.

If that's the case, do you have any other evidence that you're aware of that would suggest that Allergan or Actavis supported the Wisconsin Pain and Policy Group, that's not cited in your appendix?

A. If I cited it in the appendix I would -- and it's not appearing in this document, I would really want to go back and see what I was referring to.

Q. Okay. As you sit here today, though, you don't have any other evidence that Allergan supported the Pain and Policy Group; correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: So I am not intimately familiar with the various Allergan subsidiaries or predecessors. So I wouldn't want to make that kind of global statement without double-checking the source and also verify that there's not some subsidiary that did contribute.

Q. BY MS. RIVERA: Okay. But as you sit here today, you don't have any other evidence that you can point to; correct?

A. Not right now.

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Q. Okay. Three more quick questions.

Can you identify any payments to a KOL by Allergan?

A. Well, this $50,000, if I could verify that, would serve.

Q. Okay. Other than that. And that's not a KOL; right?

A. Well, it's founded and led by Dahl and Joranson, who are definitely KOLs.

Q. Let me try it again.

If you look at pages 19 to 22 of your report where you discuss KOLs that are sponsored by manufacturers --

A. Uh-huh.

Q. -- you don't see any reference to Allergan there, do you?

A. No. I'm not seeing any other reference.

MS. RIVERA: Okay. That's all I have. Pass the witness.

Off the record, yes, please.

THE VIDEOGRAPHER: Going off the record, the time is 5:07 p.m.

(Discussion off the record.)

THE VIDEOGRAPHER: Back on the record, the time is 5:09 p.m.

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EXAMINATION

Q. BY MS. LEIBELL: Good afternoon, Dr. Lembke. My name is Martha Leibell and I represent Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Actavis, LLC, Actavis Pharma, Inc., and Watson Laboratories, Inc., in the current litigation.

Can you tell me what medicines Actavis, LLC manufactures or sells?

A. Yes. Is Actavis a subsidiary of Teva?

Q. It is a separate entity. I'm asking only about Actavis, LLC.

A. I believe that all of the opioid manufacturers, the defendants in this litigation, have manufactured some form, either branded or generic hydrocodone and oxycodone.

Q. Okay. And is it the same answer for Actavis Pharma, Inc.?

A. Yes, same answer for Actavis Pharma, Inc.

Q. And same question for Watson Laboratories, Inc.?

A. Yes, I believe so.

Q. Did you review any package inserts or labels for any of the medicines those three entities manufacture or sell?

A. In my career, I have reviewed package inserts for many different opioids, and I'm sure that has

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included products that your defendant client sells.
Q. For purposes of preparing for the instant litigation, have you reviewed any package inserts for any drugs manufactured or sold by those three entities?
A. No.
Q. In Appendix 1 to your report, you do not identify any promotional materials published by Actavis, LLC, Actavis Pharma, Inc., or Watson Laboratories, Inc.; correct?
A. Correct.
Q. Are you aware that these three entities manufacture and/or sell generic opioid medicines?
A. Yes.
Q. Are you aware that generic opioid medicines are not marketed or promoted other than informing the public of availability and pricing?
MR. ARBITBLIT: Object to form.
THE WITNESS: I'm aware of that, but I would add that marketing for branded products influenced the prescribing and supply of generic products, and in that sense, the result is effectively the same for branded and generic products.
Q. BY MS. LEIBELL: Are you aware of a single person in Nassau County that was harmed as a result of a medically inappropriate generic opioid prescription

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manufactured or sold by these three entities?
MR. ARBITBLIT: Object to form.
THE WITNESS: Not by name.
Q. BY MS. LEIBELL: Same question for Suffolk County.
A. Not by name. And I would also refer you back to my answer to similar questions from other defendants just regarding the overall influence of opioid manufacturers, distributors and pharmacies in increasing the supply, which also apply to these questions here.
Q. Thank you. I was paying close attention all day, but I am asking questions specifically about my clients.
And are you aware of a single person in New York state that was harmed as a result of a medically inappropriate generic opioid prescription manufactured or sold by the three entities I mentioned?
A. Not by name.
Q. Are you aware that Actiq and Fentora are TIRF medicines?
MR. ARBITBLIT: Object to form.
THE WITNESS: I don't know what a TIRF medicine is.
Q. BY MS. LEIBELL: Well, I can represent that that stands for transmucosal immediate-release fentanyl.

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A. Oh. Yes, I do know what that is.
Q. Okay.
A. I have not heard it referred to as a TIRF medicine.
Q. Are you aware that they are both -- Actiq and Fentora are both short-acting opioids indicated for breakthrough cancer pain in opioid-tolerant patients?
A. Yes, I'm aware of that, but I will say that in my clinical experience, I've seen many patients who don't fit that description, who have been on Actiq and Fentora.
Q. Have you yourself ever prescribed a TIRF medicine?
A. I don't recall doing so, but I may have done very early in my career when I was still in training. I certainly have not done so in the last 20 years.
I have, however, treated many patients who have been on Actiq and Fentora. As I stated previously in the deposition, I was shocked to see patients coming into my office sucking on fentanyl lollipops.
Q. Have you ever prescribed a medication for off-label use?
A. Yes, I have.
Q. Do you know what the TIRF REMS program is?
A. Yes, I do.
Q. Can you tell me what that stands for?

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A. Well, REMS stands for Risk Evaluation and Mitigation Strategy. And again, I've not heard this term TIRF before, but transmucosal immediate-release medications are associated with a very specific REMS in order to -- that doctors are required to take as part of their responsibility before they prescribe or as they are prescribing these opioids.
Q. And are you aware that the TIRF REMS program was implemented in March 2012?
MR. ARBITBLIT: Object to form.
THE WITNESS: I'm not recalling the specific date, but that sounds about right.
Q. BY MS. LEIBELL: And are you aware that the TIRF REMS program requires an FDA-approved medication guide to be provided to patients before the medication is dispensed in an outpatient setting?
A. Can you repeat the question?
Q. Sure.
Are you aware that the TIRF REMS program requires an FDA-approved medication guide to be provided to patients before the medicine is dispensed in an outpatient setting?
A. I didn't remember that, but I believe you.
Q. And do you know whether or not medication guides usually contain product labels?

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A. I would really want to see the specific medication guide before I could comment on that. I can say that I have reviewed the REMS. I've personally reviewed the REMS for transmucosal immediate-release medications, and I think they're inadequate in order to properly educate doctors about the risks and benefits of opioids.

Q. In what respect are they inadequate?

A. I think they perpetrate many of the misleading messages along the lines of opioids being a safe and effective treatment for chronic pain and that the risk is relatively low.

They also spend very little time in general educating prescribers on addiction, what it is, how to screen and intervene, how to monitor patients. The majority of the time is spent on how to initiate opioids, how to maintain opioids, how to switch from one opioid to another.

Q. Are you aware that prescribers are required to certify that they understand the risks of abuse, potential harm from these opioids?

A. Yes, I am. But I don't think that that has made much inroads in mitigating those risks. I am familiar with cases of individuals who engaged in a -- physicians who engaged in egregious overprescribing, who documented

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that they took these REMS, but clearly their practice was not informed by safe opioid prescribing.

Q. Are you aware that patients also must certify that they've received medication guides from their prescribers before they can be dispensed these medications?

A. I don't remember that, but I believe you.

Q. And are you aware that the patient form component requires each patient prescriber to agree that they each understand the risks, consequences, and approved uses of TIRF medicines?

A. Thank you for telling me that. That's good to know. I would highlight, though, a paper that just came out in the last month by Hayward, et al., which looked at the --

Q. I'm so sorry to stop you just because I'm very short on time.

A. Yes. Specifically that paper says that -- that REMS is not showing that it's having an impact.

Q. Okay. I will turn to my next few final questions.

In Appendix 1 to your report, you list promotional messages that you identify as misleading and identify certain defendants' promotional messages; correct?

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A. That is correct.

Q. Teva Pharmaceuticals USA is not one of those defendants; correct?

A. It is not listed in Appendix 1, that is correct.

Q. Cephalon, Inc., is not one of those defendants listed in Appendix 1; correct?

A. That is correct; however, I do refer to Cephalon, Inc., in my report when I discuss the influence of the opioid pharmaceutical industry. I'm happy to turn to that.

Q. That's okay. Would you identify -- can you tell me --

A. Please do look at that, though, when you have a moment because I would like that to be part of my -- my response. And I understand you don't have much time.

Q. I have reviewed it.

A. Great.

Q. Have you identified any allegedly misleading promotional messages that were published by Cephalon, Inc., or Teva Pharmaceuticals USA, Inc., in preparation for this litigation?

A. So I have reviewed the way that Cephalon, Inc., promoted guidelines and professional organizations --

Q. I'm asking a very specific question about materials published by those two entities.

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A. Have I reviewed --

Q. Yes.

A. -- promotional materials published by those two entities; is that what you're asking me?

Q. Correct. In furtherance of this litigation.

A. No.

Q. Okay. Are you aware of any prescriber in Nassau County who since 2012 was not aware of the risks and indications of Actiq or Fentora before he or she wrote an Actiq or Fentora prescription?

A. Not by name, but generally, I am aware of prescribers in the state of New York who were influenced by the misleading messaging of opioid manufacturers regarding -- and including fentanyl lollipops.

Q. Same question for Suffolk County and New York State?

A. Yes, same answer.

Q. Are you aware of a single person in New York State, Suffolk County, or Nassau County that was harmed as a result of a medically inappropriate Actiq or Fentora prescription?

A. Not by name.

MS. LEIBELL: Thank you, Dr. Lembke.

Off the record.

THE VIDEOGRAPHER: Going off the record, the

time is 5:20 p.m.
(Discussion off the record.)
THE VIDEOGRAPHER: Back on the record, the time is 5:21 p.m.
EXAMINATION
Q. BY MS. RODGERS: Good afternoon, Dr. Lembke. My name is Megan Rodgers. I'm with the firm Covington & Burling, and I represent McKesson. I have just a few questions for you today.
Do you agree that in the treatment of pain, true addiction is uncommon?
MR. ARBITBLIT: Object to form.
THE WITNESS: What do you mean by "true addiction"?
Q. BY MS. RODGERS: What do you understand that phrase to mean?
MR. ARBITBLIT: Object to form.
THE WITNESS: Well, I'm wondering why you qualify it with the word "true."
Q. BY MS. RODGERS: Let me ask it a slightly different way.
Do you agree that in the treatment of pain, addiction is uncommon?
MR. ARBITBLIT: Object to form.
THE WITNESS: I disagree.

Q. BY MS. RODGERS: Is that a misleading statement?
A. Yes, it is.
Q. Is that the kind of statement that could result in overprescribing of opioid analgesics?
A. Yes, it is.
Q. Do you agree that individuals should not be reluctant to seek pain behalf because of the fear of addiction?
MR. ARBITBLIT: Object to the form.
THE WITNESS: Not -- can you rephrase that? Sorry, end of the day, and it sort of has a double negative in it.
Q. BY MS. RODGERS: Sure.
Do you agree that individuals should not be reluctant to seen pain relief because of the fear of addiction?
A. Yes.
Q. Is it a misleading statement to say that individuals should not be reluctant to seek pain relief because of the fear of addiction?
MR. ARBITBLIT: Object to form.
THE WITNESS: I'm having a little trouble with -- I realize I'm having a little bit of trouble tracking that statement. Can you rephrase it?
Q. BY MS. RODGERS: Let me ask it again.

Would you ever advise one of your clients that they should not be reluctant to seek pain relief because of the fear of addiction?
A. Oh, I see. I had misunderstood that previously.
No, I would not advise that. I would not advise that. I would say that the risk of addiction is very appropriate and necessary when it comes to taking opioids, even in the context of treatment for a medical condition.
Q. Do you think it's a misleading statement to say that individuals should not be reluctant to seek pain relief because of the fear of addiction?
MR. ARBITBLIT: Object to form.
THE WITNESS: It's a confusing phraseology, but to the extent that I think I understand what you're saying, I would agree that it is a misleading statement.
Q. BY MS. RODGERS: Is that the kind of statement that could result in overprescribing of opioids?
A. Yes.
Q. Do you agree that pain should be considered a fifth vital sign?
A. No.
Q. Is it a misleading statement to say that pain should be a considered a fifth vital sign?
A. Yes.

Q. And is that the kind of statement that could result in overprescribing of opioid analgesics?
A. Yes.
Q. Last few questions.
Do you agree that tolerance and physical dependency may be pharmacological effects of sustained use of opioid analgesics and are not synonymous with addiction?
MR. ARBITBLIT: Object to form.
THE WITNESS: As currently defined, I would agree with that statement, but whether neurobiologically those are distinct phenomenon I think is uncertain. They are certainly neurobiologically related and also phenomenologically related.
Q. BY MS. RODGERS: Is that the kind of statement, and I'll repeat it: Tolerance and physical dependency may be pharmacological effects of sustained use of opioid analgesics and are not synonymous with addiction. Is that the kind of statement that could result in overprescribing of opioid analgesics?
A. Yes.
MS. RODGERS: Thank you. I have no further questions.
MR. ARBITBLIT: All right. So before we go off the record, we have one little item that we want to

potentially correct having to do with the document produced natively as I believe, what was it, Exhibit 13, that was not the same document that was referenced in the expert's report, which does, in fact, mention funding from Allergan.

And so to the extent that the document was not the same as the one that the witness referenced, we would move to strike the testimony based upon that document.

And we have no -- it's Exhibit 14. We have no questions of the witness, but we reserve our right to strike that testimony based on the wrong document.

MR. CARTER: Doctor, are you going to read and sign?

MR. ARBITBLIT: What's the practice?

MR. CARTER: I'm asking her if she's going to read and sign.

MR. ARBITBLIT: Well, we'll take it up. We're off the record.

THE VIDEOGRAPHER: This concludes today's videotaped deposition of Dr. Anna Lembke. We're off the record at 5:27 p.m.

Thank you.

(Time noted: 5:27 p.m.)

--oOo--

ACKNOWLEDGMENT OF DEPONENT

I, ANNA LEMBKE, M.D., do hereby certify that I have read the foregoing transcript of my testimony taken on 1/16/2020, and further certify that it is a true and accurate record of my testimony (with the exception of the corrections listed below):

Page	Line	Correction

_____

ANNA LEMBKE, M.D.

SUBSCRIBED AND SWORN TO BEFORE ME THIS _____ DAY OF _____, 20___.

_____ _____

(NOTARY PUBLIC) MY COMMISSION EXPIRES:

STATE OF CALIFORNIA) ss:
COUNTY OF MARIN)

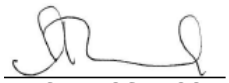
I, LESLIE ROCKWOOD ROSAS, RPR, CSR NO. 3462, do hereby certify:

That the foregoing deposition testimony was taken before me at the time and place therein set forth and at which time the witness was administered the oath;

That testimony of the witness and all objections made by counsel at the time of the examination were recorded stenographically by me, and were thereafter transcribed under my direction and supervision, and that the foregoing pages contain a full, true and accurate record of all proceedings and testimony to the best of my skill and ability.

I further certify that I am neither counsel for any party to said action, nor am I related to any party to said action, nor am I in any way interested in the outcome thereof.

IN WITNESS WHEREOF, I have subscribed my name this 20th day of January, 2020.



LESLIE ROCKWOOD ROSAS, RPR, CSR NO. 3462

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New York Code

Civil Practice Law and Rules

Article 31 Disclosure, Section 3116

(a) Signing. The deposition shall be submitted to the witness for examination and shall be read to or by him or her, and any changes in form or substance which the witness desires to make shall be entered at the end of the deposition with a statement of the reasons given by the witness for making them. The deposition shall then be signed by the witness before any officer authorized to administer an oath. If the witness fails to sign and return the deposition within sixty days, it may be used as fully as though signed. No changes to the transcript may be made by the witness more than sixty days after submission to the witness for examination.

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VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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